



AZIENDA OSPEDALIERA UNIVERSITARIA

DELIBERAZIONE DELLA DIRETTRICE GENERALE

OGGETTO:

L'Estensore:

Proposta N. Del

Allegati:

Numero imputazione spesa Imputazioni di spesa

Data imputazione spesa

Si autorizza l'imputazione della spesa sul conto e l'esercizio indicati entro il limite del budget annuale assegnato al centro di costo richiedente.

Nulla osta, in quanto conforme alle norme di contabilità.
Il Direttore Area Economica Finanziaria

Parere

Il Direttore
Amministrativo

La Direttrice
Generale

Dott.ssa Maria Grazia Furnari

Parere

Il Direttore
Sanitario

La Direttrice Generale dell'AOUP "Paolo Giaccone" di Palermo, Dott.ssa Maria Grazia Furnari, nominata con D.P. n.324 serv.1°/S.G. del 21 giugno 2024 e assistita dal segretario verbalizzante adotta la seguente delibera sulla base della proposta di seguito riportata.

Il Segretario verbalizzante



AZIENDA OSPEDALIERA UNIVERSITARIA

LA DIRETTRICE GENERALE

- PRESO ATTO** che presso l'AIFA è stato istituito il Centro di Coordinamento nazionale dei Comitati Etici Territoriali e ricostituito con il Decreto del Ministro della Salute del 27/05/2021, garante dell'omogeneità delle procedure e del rispetto dei termini temporali;
- PRESO ATTO** dell'entrata in vigore in data 31/01/2022 del nuovo Regolamento (EU) n. 536/2014 del Parlamento Europeo sulla sperimentazione clinica di medicinali per uso umano;
- VISTI** il Decreto 26 gennaio 2023 recante: "individuazione di quaranta comitati etici territoriali (di seguito indicato con DM 40 CET);
- il Decreto del 27 gennaio 2023, del Ministero della Salute recante misure relative all'individuazione e competenze dei Comitati Etici Territoriali;
- il Decreto 30.01.2023 recante: "definizione dei criteri per la composizione e il funzionamento dei comitati etici territoriali";
- PRESO ATTO** che, con delibera n. 916 del 30/06/2023 e ss.mm.ii., è stato istituito il CET (Comitato Etico Territoriale) e la Segreteria Tecnico Scientifica, in applicazione al Decreto Regionale n. 541/2023;
- che con delibera n. 1072 del 03.08.2023 è stato recepito il D.A. dell'Assessorato Salute RS n. 746 del 25.07.2023, successivamente integrato dalla nota n. 57116 "corretta applicazione art. 2 commi 5e 6";
- VISTA** la delibera n. 668 del 13/06/2024 di sottoscrizione della Convenzione economica tra l'AOUP e per essa l'UOC di Ematologia e la Società ICON CLINICAL RESEARCH LIMITED, per effettuare la Sperimentazione Clinica dal titolo: "MAGNETISMM-32 A PHASE 3, OPEN LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMAB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB, DEXAMETHASONE (PvD) OR CARFILZOMIB, DEXAMETHASONE (KD) IN PARTECIPANTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA WHO RECEIVED



AZIENDA OSPEDALIERA UNIVERSITARIA

PRIOR ANTI-CD38 DIRECTED THERAPY. Protocollo: MAGNETISSM-32
- Codice EU CT: 2023-507871-23-00 - Sperimentatore: Prof. Cirino Botta;

DATO ATTO che in data 28/01/2025 il Promotore ha ricevuto il Provvedimento AIFA che autorizza l'emendamento PA 4 per adeguare il budget al Protocollo di Studio e per informare che i contratti saranno firmati da Pfizer Inc. e non più come avvenuto in precedenza, da ICON;

VISTO l' Emendamento 1 sottoscritto e allegato alla Convenzione tra l'AOUP e la Società Pfizer Inc., per effettuare la Sperimentazione Clinica Protocollo: MAGNETISSM-32;

Per i motivi in premessa citati che qui si intendono ripetuti e trascritti

DELIBERA

Di prendere atto dell' Emendamento 1 sottoscritto e allegato, come parte sostanziale e integrante alla convenzione tra l'Azienda Ospedaliera Universitaria Policlinico e per essa l'UOC di Ematologia e la Società Pfizer Inc., per effettuare la Sperimentazione Clinica dal titolo: "MAGNETISSM-32 A PHASE 3, OPEN LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMAB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB, DEXAMETHASONE (PvD) OR CARFILZOMIB, DEXAMETHASONE (KD) IN PARTECIPANTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA WHO RECEIVED PRIOR ANTI-CD38 DIRECTED THERAPY. Protocollo: MAGNETISSM-32 - Codice EU CT: 2023-507871-23-00 - Sperimentatore: Prof. Cirino Botta;

di prendere atto che i proventi derivanti dallo Sponsor per la conduzione dello Studio, verranno ripartiti in conformità all'art. 4 - Aspetti economici- finanziari – del Regolamento Aziendale disciplinante gli aspetti procedurali, amministrativi ed economici degli studi Osservazionali, delle Sperimentazioni cliniche, dei Dispositivi Medici e delle Iniziative di Ricerca afferenti all'AOUP approvato con Delibera n . 1152 dell' 08/11/2024

EMENDAMENTO N. 1 AL

AMENDMENT #1 TO

CONTRATTO PER STUDIO CLINICO

CLINICAL STUDY AGREEMENT

tra

Between

Pfizer Inc., Delaware Corporation, con sede legale in 66 Hudson Boulevard East, New York, NY 10001, USA (d'ora innanzi denominato "Promotore" o "Pfizer

Pfizer Inc., a Delaware Corporation with a place of business at 66 Hudson Boulevard East, New York, NY 10001, USA (hereinafter the "Sponsor" or "Pfizer")

e

and

AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO "PAOLO GIACCONE" DI PALERMO (d'ora innanzi denominato/a "Ente"), con sede legale in Palermo Via del Vespro 129 C.F. e P. IVA n. 05841790826, in persona della Direttrice Generale, Dott.ssa Maria Grazia Furnari, munita di idonei poteri di firma del presente atto

AZIENDA HOSPITAL UNIVERSITARIA POLICLINICO "PAOLO GIACCONE" DI PALERMO (hereinafter referred to as the "Entity"), with registered office in PALERMO Via del Vespro 129, Fiscal Code and VAT no. 05841790826, represented by the General Manager, Dr. Maria Grazia Furnari, with the appropriate powers to sign this document

di seguito singolarmente/collettivamente **"la Parte/le Parti"**.

hereinafter individually/collectively **"the Party/the Parties"**.

Protocollo Pfizer n.C1071032

Pfizer Protocol # C1071032

Il presente Emendamento è in vigore dalla data di ultima firma.

This Amendment is effective as of last signature date.

PREMESSO CHE

WHEREAS

- il presente Emendamento n. 1 riguarda il contratto per studio clinico tra Pfizer e l'Ente con decorrenza da 13 giugno 2024, riguardante la conduzione della sperimentazione clinica dal titolo **"MAGNETISMM-32 A PHASE 3, OPEN-LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMAB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB,**

- this Amendment #1 relates to the clinical investigation agreement between Pfizer and Entity with an effective date of 13 June 2024, that covers the conduct of the clinical trial entitled **"MAGNETISMM-32 A PHASE 3, OPEN-LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMAB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB,**

DEXAMETHASONE (PVd) OR CARFILZOMIB, DEXAMETHASONE (Kd) IN PARTICIPANTS WITH RELAPSED/ REFRACTORY MULTIPLE MYELOMA WHO RECEIVED PRIOR ANTI-CD38 DIRECTED THERAPY"" (di seguito **"Sperimentazione"**), con Protocollo C1071032 (di seguito il **"Protocollo"**) e codice EudraCT n. 2023-507871-23-00;

- L'Emendamento sostanziale relativo al PA 3 è stato approvato dal CET nella seduta del 09 aprile 2024, con Decisione in data 7 maggio 2024 (AIFA 0056954-06/05/2024);

- L'Emendamento sostanziale relativo al PA 4 è stato approvato dal CET nella seduta del 10/12/2024, con Decisione in data 29/01/2025 (AIFA no. 0011693 del 28/01/2025);

- Le parti accettano le seguenti modifiche della Convenzione:

1. Le specifiche dello Studio e le relative voci sono state riviste a seguito dell'Emendamento al protocollo n.3 del 24 aprile 2024 e dell'Emendamento al Protocollo n.4 del 18 Luglio 2024, come segue:

PA3 :

Braccio A

- ✓ I seguenti test aggiunti come fatturati in base agli altri costi a livello di studio
 - test HBV; HBSAG, HBCAB e HBBSAB - non programmato (laboratorio locale)
 - carico virale del DNA HBV (analisi di laboratorio locale)
 - Test di anticorpi HCV (analisi di laboratorio locale)

DEXAMETHASONE (PVd) OR CARFILZOMIB, DEXAMETHASONE (Kd) IN PARTICIPANTS WITH RELAPSED/ REFRACTORY MULTIPLE MYELOMA WHO RECEIVED PRIOR ANTI-CD38 DIRECTED THERAPY"" (hereinafter the **"Trial"**), which regards the Protocol C1071032(hereinafter the **"Protocol"**), code EudraCT n. 2023-507871-23-00;

Substantial Amendment for PA 3 has been approved by CET on 09 april 2024, with Decision on 7 may 2024, (AIFA 0056954-06/05/2024);

-Substantial Amendment for PA 4 has been approved by CET on 10/12/2024, with Decision 29/01/2025, (AIFA approval no. 0011693 of 28/01/2025);

The parties agree to the following modifications in the Agreement:

1. Study specifications and related assumptions have been revised as follows after Protocol Amendment 3 dated April 24, 2024 and Protocol Amendment 4 dated 18 July 2024, as follows:

PA3:

Arm A

- ✓ The following tests added as invoiced under the Other Study Level Costs
 - HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)
 - HBV DNA viral load (local lab analysis)
 - HCV antibody testing (local lab analysis)

- Anticorpo HIV-1 e HIV-2, singolo dosaggio (analisi di laboratorio locale)

- HIV-1 and HIV-2 antibody, single assay (local lab analysis)

ARM B (EPD)

- ✓ Per l'elemento di linea "Cicli aggiuntivi - D15" questo dovrebbe essere pagato in base alla fatturazione
- ✓ I seguenti test aggiunti come fatturati in base agli altri costi a livello di studio
 - test HBV; HBSAG, HBCAB e HBSAB - non programmato (laboratorio locale)
 - carico virale del DNA HBV (analisi di laboratorio locale)
 - Test di anticorpi HCV (analisi di laboratorio locale)
 - Anticorpo HIV-1 e HIV-2, singolo dosaggio (analisi di laboratorio locale)

Arm B (EPd)

- ✓ For the "additional cycles – D15" line item this should be paid based on invoiced
- ✓ The following tests added as invoiced under the Other Study Level Costs
 - HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)
 - HBV DNA viral load (local lab analysis)
 - HCV antibody testing (local lab analysis)
 - HIV-1 and HIV-2 antibody, single assay (local lab analysis)

Braccio B (KD)

- ✓ I seguenti test aggiunti come fatturati in base agli altri costi a livello di studio
 - test HBV; HBSAG, HBCAB e HBBSAB - non programmato (laboratorio locale)
 - carico virale del DNA HBV (analisi di laboratorio locale)
 - Test di anticorpi HCV (analisi di laboratorio locale)
 - Anticorpo HIV-1 e HIV-2, singolo dosaggio (analisi di laboratorio locale)

Arm B (Kd)

- ✓ The following tests added as invoiced under the Other Study Level Costs
 - HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)
 - HBV DNA viral load (local lab analysis)
 - HCV antibody testing (local lab analysis)
 - HIV-1 and HIV-2 antibody, single assay (local lab analysis)

ARM B (PVD)

- ✓ I seguenti test aggiunti come fatturati in base agli altri costi a livello di studio
 - test HBV; HBSAG, HBCAB e HBBSAB - non

Arm B (PVd)

- ✓ The following tests added as invoiced under the Other Study Level Costs

programmato (laboratorio locale)

O carico virale del DNA HBV (analisi di laboratorio locale)

O Test di anticorpi HCV (analisi di laboratorio locale)

O Anticorpo HIV-1 e HIV-2, singolo dosaggio (analisi di laboratorio locale)

- HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)
- HBV DNA viral load (local lab analysis)
- HCV antibody testing (local lab analysis)
- HIV-1 and HIV-2 antibody, single assay (local lab analysis)

PA4:

Braccio A

- Rimosso il Laboratorio Chimico Centrale dai cicli C2D8, C2D22, C4D15, C5D15, C6D15 nell'area Costo per soggetto.
- Rimosso EBV PCR dall'area Costo per soggetto durante la visita di screening.
- Rimozione della PCR per l'adenovirus dall'area Costo per soggetto durante la visita di screening.
- Spostata la BMA per la valutazione della malattia/citogenetica/profilazione molecolare dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.

Braccio B (EPd)

- Rimosso il Laboratorio Chimico Centrale dai cicli C2D8, C2D22, C4D15, C5D15, C6D15 nell'area Costo per soggetto.
- Rimosso EBV PCR dall'area Costo per soggetto durante la visita di screening.
- Rimozione della PCR per l'adenovirus dall'area Costo per soggetto durante la visita di screening.
- Spostata la BMA per la valutazione della malattia/citogenetica/profilazione molecolare dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.

PA4:

Arm A

- Removed Central Lab Chemistry from cycles C2D8, C2D22, C4D15, C5D15, C6D15 in the Per Subject Cost area.
- Removed EBV PCR from the Per Subject Cost area at the Screening visit.
- Removed Adenovirus PCR from the Per Subject Cost area at the Screening visit.
- Moved BMA for disease assessment/cytogenetics/molecular profiling from the Per Subject Cost Area to the Additional Treatment Cost area.

Arm B (EPd)

- Removed Central Lab Chemistry from cycles C2D8, C2D22, C4D15, C5D15, C6D15 in the Per Subject Cost area.
- Removed EBV PCR from the Per Subject Cost area at the Screening visit.
- Removed Adenovirus PCR from the Per Subject Cost area at the Screening visit.
- Moved BMA for disease assessment/cytogenetics/molecular profiling from the Per Subject Cost Area to the Additional Treatment Cost area.

Braccio B (Kd)

- Rimosso il Laboratorio Chimico Centrale dai cicli C2D8 nell'area Costo per soggetto.
- Rimosso EBV PCR dall'area Costo per soggetto durante la visita di screening.
- Rimozione della PCR per l'adenovirus dall'area Costo per soggetto durante la visita di screening.
- Spostato BMA per MRD, profilazione molecolare dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.
- Spostato il BMB per il profilo proteico dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.

Braccio B (PVd)

- Rimosso il Laboratorio Chimico Centrale dai cicli C2D8, C2D22, C4D15, C5D15, C6D15 nell'area Costo per soggetto.
- Rimosso EBV PCR dall'area Costo per soggetto durante la visita di screening.
- Rimozione della PCR per l'adenovirus dall'area Costo per soggetto durante la visita di screening.
- Spostato BMA per MRD, profilazione molecolare dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.
- Spostato il BMB per il profilo proteico dall'area Costo per soggetto all'area Costo trattamento aggiuntivo.

In conformità con queste specifiche riviste dello Studio, il finanziamento massimo disponibile per l'Ente viene modificato come segue in base al completamento di tutte le visite e procedure, come ulteriormente dettagliato nell'Allegato A revisionato qui allegato (Budget dello studio e Termini di pagamento).

Arm B (Kd)

- Removed Central Lab Chemistry from cycles C2D8 in the Per Subject Cost area.
- Removed EBV PCR from the Per Subject Cost area at the Screening visit.
- Removed Adenovirus PCR from the Per Subject Cost area at the Screening visit.
- Moved BMA for MRD, Molecular Profiling from the Per Subject Cost Area to the Additional Treatment Cost area.
- Moved BMB for protein profiling from the Per Subject Cost Area to the Additional Treatment Cost area.

Arm B (PVd)

- Removed Central Lab Chemistry from cycles C2D8, C2D22, C4D15, C5D15, C6D15 in the Per Subject Cost area.
- Removed EBV PCR from the Per Subject Cost area at the Screening visit.
- Removed Adenovirus PCR from the Per Subject Cost area at the Screening visit.
- Moved BMA for MRD, Molecular Profiling from the Per Subject Cost Area to the Additional Treatment Cost area.
- Moved BMB for protein profiling from the Per Subject Cost Area to the Additional Treatment Cost area.

In accordance with these revised Study specifications, the maximum funding available to Entity is revised as follows based upon completion of all visits and procedures, as further detailed in the attached revised Attachment A (Study Budget and Payment Terms).

- Arm "A" : € 18.780,98 per paziente;
 - Arm "B" (PVd): € 18.936,13 per paziente;
 - Arm "B" (Kd): € 19.859,49 per paziente;
 - Arm "B" (Epd): €16.353,97 per paziente
 per n. 5 pazienti;

- Arm "A" : €18.780,98 per patient
 - Arm "B" (PVd): € 18.936,13 per patient
 - Arm "B" (Kd): € 19.859,49 per patient
 - Arm "B" (Epd): € 16.353,97 per patient;
 For 5 patients
 omissis

4. Si allega l'Allegato A rivisto (Budget dello studio e Termini di pagamento).

4.A revised Attachment A (Study Budget and Payment Terms) is attached.

Le parti hanno concordato che le seguenti modifiche all'Allegato A-Exhibit 1, dovute agli Emendamenti 3 e 4 del Protocollo, saranno implementabili a partire dalle date di approvazione etica.

The parties have agreed to the following modifications to Exhibit 1-Annex A due to Protocol Amendments 3 and 4 are effective as off their approval dates.

Tutti gli altri termini del Contratto restano in vigore.

All other terms of the Agreement remain in effect.

Il presente Emendamento n. 1 viene sottoscritto digitalmente ai sensi dell'Articolo 24 del Decreto Legislativo 82/2005, in conformità a quanto previsto dall'Articolo 15 comma 2A della Legge 241/1990 come integrato dall'Articolo 6 del Decreto Legge 18/10/2012 n. 179, convertito in Legge 17/12/2012 n. 22. Tutte le tasse e le imposte relative a o derivanti dalla stipula del presente Emendamento n.1, compresa l'imposta di bollo sull'originale digitale di cui all'Articolo 2 della tabella nell'Allegato A – tariffa parte I del DPR 642/1972, e l'imposta di registro, devono essere corrisposte in conformità alla normativa applicabile. L'imposta di bollo è pagata elettronicamente da Pfizer Inc., con sede legale in 66 Hudson Boulevard East, New York, NY,10001, USA, ai sensi dell'art. 15 del D.P.R. 642 del 1972 (Autorizzazione dell'Agenzia delle

This Amendment #1 is signed digitally in accordance with Article 24 of legislative decree 82/2005, in accordance with the provisions of Article 15 paragraph 2A of Law 241/1990 as supplemented by article 6, decree law 18/10/2012, no. 179, converted into Law no. 22 of 17/12/2012. All the taxes and duties relating to or resulting from the stipulation of this Amendment #1 including the revenue stamp on the digital original as referred to in Article 2 of the table in Annex A – tariff part I of Presidential Decree 642/1972, and the registration tax, must be paid in accordance with the applicable regulations. Stamp duty is paid electronically by Pfizer Inc., with registered office at 66 Hudson Boulevard East, New York, NY, 10001, USA, pursuant to art. 15 of the Presidential Decree (D.P.R.) 642 of 1972 (Authorization of the

Entrate di Roma n. 12/2025)

Revenue Agency of Rome with number
12/2025).

ACCETTATO E CONCORDATO DA E TRA/ ACCEPTED AND AGREED TO BY:

Per Pfizer Inc.

Il procuratore delegato / The delegated attorney

Dott./Dr.Gustavo Luis Martiarena

(firmato digitalmente / digitally signed)

Per l'Ente/for the Entity

Il Direttore Generale/ The General Manager

Dr. Maria Grazia Furnari

(firmato digitalmente / digitally signed)

Exhibit 1 – Annex A/ Appendice 1 - Allegato A -PA3

ARM A

COMPOUND :	Elranatamab	AMENDMENT :	PA3	INVESTIGATOR:	Cirino Botta			
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm A	INSTITUTION:	AOU P. Giaccone			
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.			CCID:	1031			
COUNTRY/Currency :	Italy - EUR							
OVERHEAD	16,00%							

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1	f	C3D8	f	C3D15
Informed Consent		43.00	1.0	43	1.00	43.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75	1.00	75.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	16.0	320	1.00	20.00	1.00	20.00		0.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	1.00	155.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864		0.00	1.00	72.00		0.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00
Full Neurologic Exam		82.00	1.0	82	1.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Neurologic Exam		69.00	15.0	1035		0.00	1.00	69.00		0.00		0.00		69.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00	1.00	69.00
ECOG PS		20.00	1.0	20	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	1.00	61.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00	1.00	116.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38.00	23.0	874	1.00	38.00	1.00	38.00		0.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00		0.00	1.00	38.00
Saliva sample for germline comparator		24.00	1.0	24		0.00	1.00	24.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 testing	Local test	83.00	1.0	83	1.00	83.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Elrantamab administration	SC injection	28.00	41.0	1148		0.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
Pharmacy Fee - IV Premedication /SC elrantamab	Prep and dispense	45.00	41.0	1845		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Blood sample for elranatamab PK		24.00	11.0	264		0.00	2.00	48.00	2.00	48.00	1.00	24.00		0.00		0.00	1.00	24.00		0.00		0.00		0.00	1.00	24.00		0.00		0.00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRIS/CAUS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37.00	149.5	5531.5	4.25	157.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25
Admin/Data Entry Fee		31.00	90.0	2790	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection	232.00	1.0	232	1.00	232.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
BMB for protein profiling	Sample collection	314.00	1.0	314	1.00	314.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114.00	1.0	114	1.00	114.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR		42.00	1.0	42	1.00	42.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
EBV PCR		58.00	1.0	58	1.00	58.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Adenovirus PCR		46.00	1.0	46	1.00	46.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			16,716.50		1,602.25		651.50		303.25		317.25		498.25		293.25		487.50		293.25		498.25		293.25		487.50		255.25		382.25
	PSC Subtotal with Overhead			19,391.14		1,858.61		755.74		351.77		368.01		577.97		340.17		565.50		340.17		577.97		340.17		565.50		296.09		443.41

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 14	VISIT 15	VISIT 16	VISIT 17	VISIT 18	VISIT 19	VISIT 20	VISIT 21	VISIT 22	VISIT 23	VISIT 24	VISIT 25	VISIT 26
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f C3D22	f C4D1	f C4D8	f C4D15	f C4D22	f C5D1	f C5D8	f C5D15	f C5D22	f C6D1	f C6D8	f C6D15	f C6D22
Informed Consent		43.00	1.0	43	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	16.0	320	0.00	1.00	20.00	0.00	0.00	0.00	1.00	20.00	0.00	0.00	0.00	1.00	20.00
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864	0.00	1.00	72.00	0.00	0.00	0.00	1.00	72.00	0.00	0.00	1.00	72.00	0.00
Full Neurologic Exam		82.00	1.0	82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Targeted Neurologic Exam		69.00	15.0	1035	0.00	1.00	69.00	0.00	0.00	0.00	1.00	69.00	0.00	0.00	1.00	69.00	0.00
ECOG PS		20.00	1.0	20	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696	0.00	1.00	116.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	116.00	0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAbS against elranatamab (Arm A)	38.00	23.0	874	0.00	1.00	38.00	0.00	1.00	38.00	0.00	1.00	38.00	0.00	1.00	38.00	0.00
Saliva sample for germline comparator		24.00	1.0	24	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SARS-CoV-2 testing	Local test	83.00	1.0	83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Elranatamab administration	SC injection	28.00	41.0	1148	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00
Pharmacy Fee - IV Premedication/SC elranatamab	Prep and dispense	45.00	41.0	1845	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00
Blood sample for elranatamab PK		24.00	11.0	264	0.00	1.00	24.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/ICANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37.00	149.5	5531.5	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25
Admin/Data Entry Fee		31.00	90.0	2790	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection	232.00	1.0	232	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BMB for protein profiling	Sample collection	314.00	1.0	314	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114.00	1.0	114	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CMV PCR		42.00	1.0	42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBV PCR		58.00	1.0	58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Adenovirus PCR		46.00	1.0	46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	PSC Subtotal w/out Overhead			16,716.50	255.25	603.50	255.25	293.25	255.25	463.50	255.25	293.25	255.25	579.50	255.25	293.25	255.25
	PSC Subtotal with Overhead			19,391.14	296.09	700.06	296.09	340.17	296.09	537.66	296.09	340.17	296.09	672.22	296.09	340.17	296.09

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36		VISIT 37		VISIT 38		VISIT 39	
					f	C7D1	f	C7D8	f	C7D15	f	C7D22	f	C8D1	f	C8D8	f	C8D15	f	C8D22	f	C9D1	f	C9D8	f	C9D15	f	C9D22	f	C10D1
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAl and PGIC	20,00	16,0	320	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B), PT/INR, Blood sample for sBcMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAbS against elranatamab (Arm A)	38,00	23,0	874	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elranatamab administration	SC injection	28,00	41,0	1148	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00
Pharmacy Fee - IV Premedication /SC elranatamab	Prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
Blood sample for elranatamab PK		24,00	11,0	264	1,00	24,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	24,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/CANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	149,5	5531,5	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50
Admin/Data Entry Fee		31,00	90,0	2790	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBSAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR		58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR		46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			16.716,50		487,50		255,25		255,25		255,25		463,50		255,25		255,25		255,25		463,50		255,25		255,25		255,25		487,50
	PSC Subtotal with Overhead			19.391,14		565,50		296,09		296,09		296,09		537,66		296,09		296,09		296,09		537,66		296,09		296,09		296,09		565,50

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 40		VISIT 41		VISIT 42		VISIT 43		VISIT 44		VISIT 45		VISIT 46	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C10D8	f	C10D15	f	C10D22	f	EOT	f	FU	f	LTFU	f	LTDA
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	16,0	320		0,00		0,00		0,00	1,00	20,00	1,00	20,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00		0,00		0,00	1,00	72,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035		0,00		0,00		0,00	1,00	69,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm BJ, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and Nabs against elranatamab (Arm A)	38,00	23,0	874		0,00		0,00		0,00	1,00	38,00		0,00		0,00	1,00	38,00
		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00
		83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00
		28,00	41,0	1148	1,00	28,00	1,00	28,00	1,00	28,00		0,00		0,00		0,00		0,00
		45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00		0,00
Saliva sample for germline comparator	Local test	24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	SC injection	28,00	41,0	1148	1,00	28,00	1,00	28,00	1,00	28,00		0,00		0,00		0,00		0,00
Elranatamab administration	Prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00		0,00
Pharmacy Fee - IV Premedication /SC elranatamab		24,00	11,0	264		0,00		0,00		0,00	1,00	24,00		0,00		0,00		0,00
Blood sample for elranatamab PK																		
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/ICANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	149,5	5531,5	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	1,50	55,50	1,50	55,50
		31,00	90,0	2790	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	1,00	31,00	1,00	31,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114				0,00				0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42				0,00				0,00		0,00		0,00		0,00
EBV PCR		58,00	1,0	58				0,00				0,00		0,00		0,00		0,00
Adenovirus PCR		46,00	1,0	46				0,00				0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			16.716,50		255,25		255,25		255,25		521,25		343,25		86,50		124,50
	PSC Subtotal with Overhead			19.391,14		296,09		296,09		296,09		604,65		398,17		100,34		144,42

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15
CHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
IUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
hest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
hest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elranatamab	IV administration Refer to Table 5	95,00	3,0	285		0,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39	1,00	39,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00	1,00	38,00		0,00		0,00		0,00		0,00		0,00		0,00
ospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00	2,00	1.400,00	1,00	700,00		0,00		0,00		0,00		0,00		0,00		0,00
rine Pregnancy Test	WOCBP only	19,00	16,0	304	1,00	19,00	1,00	19,00		0,00	1,00	19,00	1,00	19,00	1,00	19,00	1,00	19,00		0,00		0,00
erum Pregnancy Test	WOCBP only	27,00	16,0	432	1,00	27,00	1,00	27,00		0,00	1,00	27,00	1,00	27,00	1,00	27,00	1,00	27,00		0,00		0,00
ARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00	1,00	71,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00
ARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00	1,00	60,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00
MV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BV PCR	If screening test performed >7 days	58,00	1,0	58		0,00	1,00	58,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
denovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00	1,00	46,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.716,50		1.602,25		651,50		303,25		317,25		498,25		293,25		487,50		293,25		498,25
Additional Cost Subtotal				7.134,00		2.489,00		1.818,00		833,00		141,00		46,00		46,00		177,00		0,00		0,00
Subtotal				23.850,50		4.091,25		2.469,50		1.136,25		458,25		544,25		339,25		664,50		293,25		498,25
Overhead				3.816,08		654,60		395,12		181,80		73,32		87,08		54,28		106,32		46,92		79,72
INVESTIGATOR COST PER SUBJECT with Overhead				27.666,58		4.745,85		2.864,62		1.318,05		531,57		631,33		393,53		770,82		340,17		577,97

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D22	f	C3D1	f	C3D8	f	C3D15	f	C3D22	f	C4D1	f	C4D8	f	C4D15	f	C4D22
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elrantomab	IV administration Refer to Table 5	95,00	3,0	285		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only). Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304		0,00	1,00	19,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432		0,00	1,00	27,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.716,50		293,25		487,50		255,25		382,25		255,25		603,50		255,25		293,25		255,25
Additional Cost Subtotal				7.134,00		0,00		177,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00
Subtotal				23.850,50		293,25		664,50		255,25		382,25		255,25		780,50		255,25		293,25		255,25
Overhead				3.816,08		46,92		106,32		40,84		61,16		40,84		124,88		40,84		46,92		40,84
INVESTIGATOR COST PER SUBJECT with Overhead				27.666,58		340,17		770,82		296,09		443,41		296,09		905,38		296,09		340,17		296,09

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D1	f	C5D8	f	C5D15	f	C5D22	f	C6D1	f	C6D8	f	C6D15	f	C6D22	f	C7D1
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elrantomab	IV administration Refer to Table 5	95,00	3,0	285		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304	1,00	19,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00	1,00	19,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432	1,00	27,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00	1,00	27,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.716,50		463,50		255,25		293,25		255,25		579,50		255,25		293,25		255,25		487,50

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	f	C10D1	f	C10D8	f	C10D15	f	C10D22	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA	740,00	1,0	740			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elrantomab	IV administration Refer to Table 5	95,00	3,0	285			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114			0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304		1,00	19,00		0,00		0,00		0,00	1,00	19,00	1,00	19,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432		1,00	27,00		0,00		0,00		0,00	1,00	27,00	1,00	27,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781		1,00	71,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660		1,00	60,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46			0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.716,50			487,50		255,25		255,25		255,25		521,25		343,25		86,50		124,50
Additional Cost Subtotal				7.134,00			177,00		0,00		0,00		0,00		46,00		84,00		38,00		0,00
Subtotal				23.850,50			664,50		255,25		255,25		255,25		567,25		427,25		124,50		124,50
Overhead				3.816,08			106,32		40,84		40,84		40,84		90,76		68,36		19,92		19,92
INVESTIGATOR COST PER SUBJECT with Overhead				27.666,58			770,82		296,09		296,09		296,09		658,01		495,61		144,42		144,42

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Pharmacy start-up fee	Invoice once at start up	697,00
Admin start-up fee	Invoice once at start up	1.727,00
Record Archiving	Invoice once at study close	2.564,00
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	1.201,69
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	28,00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12

CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
BMA for disease assessment	Sample collection	269,12
Unscheduled Visit	Includes 1Hr SC and 1 Hr DE time	78,88
Anesthesia for BMA or BMB	Invoice as incurred	316,68
Triplicate 12 Lead ECG	Invoice as incurred	134,56
Additional LTFU	Paid based on EDC completion,	100,34
Additional LTDA	Paid based on EDC completion,	144,42
Additional Cycles - D1	Paid based on EDC completion,	565,50
Additional Cycles - D8	Paid based on EDC completion,	296,09
Additional Cycles - D15	Paid based on EDC completion	296,09
Additional Cycles - D22	Paid based on EDC completion,	296,09
PROs	Invoice as incurred > C10 Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC,	23,20
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed.	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally,	114,84
CMV PCR	If required locally	48,72
EBV PCR	If required locally	67,28
Adenovirus PCR	If required locally	53,36
Immunoglobulin replacement IVIG (SC administration)	Invoice as incurred	32,48
Immunoglobulin replacement IVIG (IV administration)	Invoice as incurred	110,20
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04

Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If required locally	69,60
Reconsenting	Invoice as incurred	37,00
SAE	Includes all reports and follow up	63,00
Pharmacy Close out	Invoice at study close	335,00
Plasma Cells % - local analysis	To be invoiced as incurred.	23,20
Kappa Light Chain - local analysis	To be invoiced as incurred.	32,48
HBV testing: HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Lambda Light Chain - local analysis	To be invoiced as incurred.	32,48

ARM B(EPD)

COMPOUND :	Elranatamab	AMENDMENT :	PA3	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B(EPD)	INSTITUTION:	AOU P. Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.				
COUNTRY/Currency :	Italy - EUR			CCID:	1031
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13	
			Total Number of times a procedure occurs based on PSC Structure		f	Screening	f	C1D1	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1	f	C3D15	f	C4D1	f	C4D15
Informed Consent		43,00	1.0	43	1.00	43,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1.0	75	1.00	75,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	16.0	320	1.00	20,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00	1,00	20,00	1,00	20,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1.0	155	1.00	155,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12.0	864		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00	1,00	72,00		0,00
Full Neurologic Exam		82,00	1.0	82	1.00	82,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15.0	1035		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00	1,00	69,00	1,00	69,00		0,00
ECOG PS		20,00	1.0	20	1.00	20,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1.0	61	1.00	61,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6.0	696		0,00	1,00	116,00		0,00	1,00	116,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00	1,00	116,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B), PT/INR, Blood sample for sBCMA levels, Blood sample for cDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38,00	23.0	874	1.00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00
Saliva sample for germline comparator		24,00	1.0	24		0,00	1,00	24,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1.0	83	1.00	83,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elotuzumab administration	ARM B - IV administration	95,00	16.0	1520		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00
Pharmacy Fee-Elotuzumab	ARM B - Elotuzumab Prep and dispense	45,00	16.0	720		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00
Pharmacy Fee - Oral	Oral Drug dispense	32,00	16.0	512		0,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00		0,00
Administration of premedication for elotuzumab	If administered IV - Arm B Refer to table 5	95,00	16.0	1520		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00	1,00	95,00
Pharmacy Fee - Premedication for elotuzumab	ARM B - Prep and dispense IV drug	45,00	16.0	720		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00	1,00	45,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	81.3	3006,25	4,25	157,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,50	129,50	3,25	120,25
Admin/Data Entry Fee		31,00	48.0	1488	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection	232,00	1.0	232	1.00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling	Sample collection	314,00	1.0	314	1.00	314,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114,00	1.0	114	1.00	114,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1.0	42	1.00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR		58,00	1.0	58	1.00	58,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR		46,00	1.0	46	1.00	46,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			14.624,25		1.602,25		842,50		532,25		737,25		532,25		702,50		532,25		737,25		532,25		702,50		309,25		818,50		220,25
	PSC Subtotal with Overhead			16.964,13		1.858,61		977,30		617,41		855,21		617,41		814,90		617,41		855,21		617,41		814,90		358,73		949,46		255,49

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25			
					COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C5D1	f	C5D15	f	C6D1	f	C6D15	f	C7D1	f	C8D1	f	C9D1	f	C10D1	f	EOT	f	FU	f	LTFU	f
Informed Consent			43.00	1.0	43		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history		75.00	1.0	75		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC		20.00	16.0	320	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00	1.00	20.00	1.00	20.00	1.00	20.00	1.00	20.00		0.00		0.00		0.00	
Full Physical Exam	Includes height/weight and vital signs where applicable		155.00	1.0	155		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Targeted Physical Exam	Includes height/weight and vital signs where applicable		72.00	12.0	864	1.00	72.00		0.00	1.00	72.00		0.00	1.00	72.00	1.00	72.00	1.00	72.00	1.00	72.00	1.00	72.00		0.00		0.00		0.00	
Full Neurologic Exam			82.00	1.0	82		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Targeted Neurologic Exam			69.00	15.0	1035	1.00	69.00		0.00	1.00	69.00		0.00	1.00	69.00	1.00	69.00	1.00	69.00	1.00	69.00	1.00	69.00		0.00		0.00		0.00	
ECOG PS			20.00	1.0	20		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Single 12 Lead ECG	Includes interpretation and report		61.00	1.0	61		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Triplicate 12 Lead ECG	Includes interpretation and report		116.00	6.0	696		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry,TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for ctDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)		38.00	23.0	874	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00		0.00		0.00	1.00	38.00	
	Saliva sample for germline comparator		24.00	1.0	24		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
	SARS-Cov-2 testing	Local test	83.00	1.0	83		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
	Elotuzumab administration	ARM B - IV administration	95.00	16.0	1520	1.00	95.00		0.00	1.00	95.00		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		0.00		0.00		0.00		0.00	
	Pharmacy Fee-Elotuzumab	ARM B - Elotuzumab Prep and dispense	45.00	16.0	720	1.00	45.00		0.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00		0.00		0.00		0.00	
	Pharmacy Fee - Oral	Oral Drug dispense	32.00	16.0	512	1.00	32.00		0.00	1.00	32.00		0.00	1.00	32.00	1.00	32.00	1.00	32.00	1.00	32.00		0.00		0.00		0.00		0.00	
	Administration of premedication for elotuzumab	If administered IV - Arm B Refer to table 5	95.00	16.0	1520	1.00	95.00		0.00	1.00	95.00		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		0.00		0.00		0.00		0.00	
	Pharmacy Fee - Premedication for elotuzumab	ARM B - Prep and dispense IV drug	45.00	16.0	720	1.00	45.00		0.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00		0.00		0.00		0.00	
	Includes: Distribute emergency contact card, infection reminder card , Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,		37.00	81.3	3006.25	3.50	129.50	3.25	120.25	3.50	129.50	3.25	120.25	3.50	129.50	3.50	129.50	3.50	129.50	3.50	129.50	3.25	120.25	3.25	120.25	1.50	55.50	1.50	55.50	
Study Coordinator Fee			31.00	48.0	1488	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	1.00	31.00	1.00	31.00	
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection		232.00	1.0	232		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
BMB for protein profiling	Sample collection		314.00	1.0	314		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
HBV testing	Fee includes HBsAg, HBeAb and HBsAb		114.00	1.0	114		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
CMV PCR			42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
EBV PCR			58.00	1.0	58		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Adenovirus PCR			46.00	1.0	46		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
	PSC Subtotal w/out Overhead																													
					14,624.25		702.50		220.25		818.50		220.25		702.50		702.50		702.50		702.50		497.25		343.25		86.50		124.50	
	PSC Subtotal with Overhead				16,964.13		814.90		255.49		949.46		255.49		814.90		814.90		814.90		814.90		576.81		398.17		100.34		144.42	

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1	f	C3D15	f	C4D1	f	C4D15
ECHO	Either Echo or MUGA	740.00	1.0	740	1.00	740.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
MUGA	Either Echo or MUGA	618.00	1.0	618	1.00	618.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162.00	1.0	162	1.00	162.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753.00	1.0	753	1.00	753.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39.00	1.0	39	1.00	39.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38.00	2.0	76		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Urine Pregnancy Test	WOCBP only	19.00	11.0	209	1.00	19.00	1.00	19.00		0.00		0.00		0.00	1.00	19.00		0.00		0.00		0.00	1.00	19.00		0.00	1.00	19.00		0.00
Serum Pregnancy Test	WOCBP only	27.00	11.0	297	1.00	27.00	1.00	27.00		0.00		0.00		0.00	1.00	27.00		0.00		0.00		0.00	1.00	27.00		0.00	1.00	27.00		0.00
SARS-CoV-2 PCR		71.00	1.0	71		0.00	1.00	71.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 Antigen		60.00	1.0	60		0.00	1.00	60.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR	If screening test performed >7 days	42.00	1.0	42		0.00	1.00	42.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
EBV PCR	If screening test performed >7 days	58.00	1.0	58		0.00	1.00	58.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Adenovirus PCR	If screening test performed >7 days	46.00	1.0	46		0.00	1.00	46.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal				14,624.25		1,602.25		842.50		532.25		737.25		532.25		702.50		532.25		737.25		532.25		702.50		309.25		818.50		220.25
Additional Cost Subtotal				3,171.00		2,358.00		323.00		0.00		0.00		0.00		46.00		0.00		0.00		0.00		46.00		0.00		46.00		0.00
Subtotal				17,795.25		3,960.25		1,165.50		532.25		737.25		532.25		748.50		532.25		737.25		532.25		748.50		309.25		864.50		220.25
Overhead				2,847.24		633.64		186.48		85.16		117.96		85.16		119.76		85.16		117.96		85.16		119.76		49.48		138.32		35.24
INVESTIGATOR COST PER SUBJECT with Overhead				20,642.49		4,593.89		1,351.98		617.41		855.21		617.41		868.26		617.41		855.21		617.41		868.26		358.73		1,002.82		255.49

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D1	f	C5D15	f	C6D1	f	C6D15	f	C7D1	f	C8D1	f	C9D1	f	C10D1	f	EOT	f	FU	f	LTFU	f	LTDA	
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00	
Urine Pregnancy Test	WOCBP only	19,00	11,0	209	1,00	19,00		0,00	1,00	19,00		0,00	1,00	19,00	1,00	19,00	1,00	19,00	1,00	19,00		0,00		0,00		0,00		0,00	
Serum Pregnancy Test	WOCBP only	27,00	11,0	297	1,00	27,00		0,00	1,00	27,00		0,00	1,00	27,00	1,00	27,00	1,00	27,00	1,00	27,00		0,00		0,00		0,00		0,00	
SARS-CoV-2 PCR		71,00	1,0	71		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
SARS-CoV-2 Antigen		60,00	1,0	60		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Per Subject Cost Subtotal					14.624,25		702,50		220,25		818,50		220,25		702,50		702,50		702,50		702,50		497,25		343,25		86,50		124,50
Additional Cost Subtotal					3.171,00		46,00		0,00		46,00		0,00		46,00		46,00		46,00		46,00		0,00		38,00		38,00		0,00
Subtotal					17.795,25		748,50		220,25		864,50		220,25		748,50		748,50		748,50		748,50		497,25		381,25		124,50		124,50
Overhead					2.847,24		119,76		35,24		138,32		35,24		119,76		119,76		119,76		119,76		79,56		61,00		19,92		19,92
INVESTIGATOR COST PER SUBJECT with Overhead					20.642,49		868,26		255,49		1.002,82		255,49		868,26		868,26		868,26		868,26		576,81		442,25		144,42		144,42

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	1.201,69
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	28,00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36

MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
BMA for disease assessment	Sample collection	269,12
Unscheduled Visit	Includes 1Hr SC and 1 Hr DE time	78,88
Anesthesia for BMA or BMB		316,68
Triplicate 12 Lead ECG		134,56
Additional LTFU	Paid based on EDC completion	100,34
Additional LTDA	Paid based on EDC completion	144,42
Additional Cycles - D1	Paid based on EDC completion	814,90
Additional Cycles - D15	Paid based on invoice	255,49
PROs	Invoice as incurred > C10 Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC,	23,20
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed.	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally / additional testing required	114,84
CMV PCR	If additional testing required	48,72
EBV PCR	If additional testing required	67,28
Adenovirus PCR	If additional testing required	53,36
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting	Invoice as incurred	37,00
SAE	Includes all reports and follow up	63,00
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Pharmacy Close out	Invoice at study close	335,00

ARM B(PVD)

COMPOUND :	Elranatamab	AMENDMENT :	PA3	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B(PVD)	INSTITUTION:	AOU P. Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVD) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.				CCID: 1031
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13	
			Total Number of times a procedure occurs based on PSC Structure		f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D11	f	C2D1	f	C2D4	f	C2D8	f	C2D11	f	C3D1	f	C3D4	f	C3D8	f	C3D11
Informed Consent		43,00	1,0	43	1,00	43,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75	1,00	75,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	13,0	260	1,00	20,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155	1,00	155,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82	1,00	82,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00
ECOG PS		20,00	1,0	20	1,00	20,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61	1,00	61,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	4,0	464		0,00	1,00	116,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	SREP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for sBCMA levels, Blood sample for ctDNA analysis, Serum sample for circulating proteins and/or metabolite analysis (Arm B PVD), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)	38,00	19,0	722	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00		0,00		0,00		0,00
Saliva sample for germline comparator		24,00	1,0	24		0,00	1,00	24,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing	Local test	83,00	1,0	83	1,00	83,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Bortezomib Administration	IV/SC administration	95,00	36,0	3420		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00
	Includes: Distribute emergency contact card, Infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check																													
Study Coordinator Fee		37,00	133,3	4930,25	4,25	157,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25
Admin/Data Entry Fee		31,00	41,0	1271	2,00	62,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00
BMA for MRD, Molecular Profiling	Sample collection	232,00	1,0	232	1,00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling	Sample collection	314,00	1,0	314	1,00	314,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	10,0	320		0,00	1,00	32,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00
Pharmacy Fee	IV drug prep and dispense	45,00	36,0	1620		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
Body Surface Area calculation		17,00	36,0	612		0,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114	1,00	114,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR		58,00	1,0	58	1,00	58,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR		46,00	1,0	46	1,00	46,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
			0,0	0		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			16.660,25		1.602,25		688,50		346,25		346,25		346,25		548,50		346,25		346,25		346,25		548,50		308,25		308,25		308,25
	PSC Subtotal with Overhead			19.325,89		1.858,61		798,66		401,65		401,65		401,65		636,26		401,65		401,65		401,65		636,26		357,57		357,57		357,57

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		
			Total Number of times a procedure occurs based on PSC Structure		f	C4D1	f	C4D4	f	C4D8	f	C4D11	f	C5D1	f	C5D4	f	C5D8	f	C5D11	f	C6D1	f	C6D4	f	C6D8	f	C6D11	f	C7D1	
Informed Consent		43,00	1,0	43	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	13,0	260	1,00	20,00	0,00		0,00		0,00	1,00	20,00	0,00		0,00		0,00		0,00	1,00	20,00	0,00		0,00		0,00	1,00	20,00		
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864	1,00	72,00	0,00		0,00		0,00	1,00	72,00	0,00		0,00		0,00		0,00	1,00	72,00	0,00		0,00		0,00	1,00	72,00		
Full Neurologic Exam		82,00	1,0	82	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Targeted Neurologic Exam		69,00	12,0	828	1,00	69,00	0,00		0,00		0,00	1,00	69,00	0,00		0,00		0,00		0,00	1,00	69,00	0,00		0,00		0,00	1,00	69,00		
ECOG PS		20,00	1,0	20	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	4,0	464	1,00	116,00	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00	0,00		0,00		0,00		0,00	0,00
Central Lab - includes collection, processing and shipping	SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis (Arm B Pvd), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)	38,00	19,0	722	1,00	38,00	0,00		0,00		0,00	1,00	38,00	0,00		0,00		0,00		0,00	1,00	38,00	0,00		0,00		0,00	1,00	38,00		
		24,00	1,0	24	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
		83,00	1,0	83	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
		95,00	36,0	3420	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	95,00
Study Coordinator Fee	IVI/SC administration	37,00	133,3	4930,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	
Admin/Data Entry Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	31,00	41,0	1271	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	
BMA for MRD, Molecular Profiling	Sample collection	232,00	1,0	232	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
BMB for protein profiling	Sample collection	314,00	1,0	314	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Pharmacy Fee	Oral Drug prep and dispense	32,00	10,0	320	1,00	32,00	0,00		0,00		0,00	1,00	32,00	0,00		0,00		0,00		0,00	1,00	32,00	0,00		0,00		0,00	1,00	32,00		
Pharmacy Fee	IV drug prep and dispense	45,00	36,0	1620	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	
Body Surface Area calculation		17,00	36,0	612	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
CMV PCR		42,00	1,0	42	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
EBV PCR		58,00	1,0	58	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
Adenovirus PCR		46,00	1,0	46	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
			0,0	0	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	0,00	
	PSC Subtotal w/out Overhead			16.660,25	664,50		308,25		308,25		308,25		548,50		308,25		308,25		308,25		308,25		664,50		308,25		308,25		308,25		548,50
	PSC Subtotal with Overhead			19.325,89	770,82		357,57		357,57		357,57		636,26		357,57		357,57		357,57		357,57		770,82		357,57		357,57		357,57		636,26

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36		VISIT 37		VISIT 38		VISIT 39		VISIT 40		VISIT 41			
			Total Number of times a procedure occurs based on PSC Structure		f	C7D4	f	C7D8	f	C7D11	f	C8D1	f	C8D4	f	C8D8	f	C8D11	f	C9D1	f	C9D8	f	C10D1	f	C10D8	f	EOT	f	FU	f	LTFU	f	LTDA		
Informed Consent		43.00	1.0	43		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PQoL	20.00	13.0	260		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00	1.00	20.00		0.00		0.00		
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00		0.00	1.00	72.00		0.00	1.00	72.00	1.00	72.00		0.00		0.00		
Full Neurologic Exam		82.00	1.0	82		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Targeted Neurologic Exam		69.00	12.0	828		0.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00	1.00	69.00	1.00	69.00		0.00		0.00		
ECOG PS		20.00	1.0	20		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
TriPLICATE 12 Lead ECG	Includes interpretation and report	116.00	4.0	464		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		
	SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for sBcMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolic analysis (Arm B Pivd), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)																																			
Central Lab - includes collection, processing and shipping		38.00	19.0	722		0.00		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00	1.00	38.00		0.00	1.00	38.00		0.00		0.00	1.00	38.00		
Saliva sample for germline comparator		24.00	1.0	24		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
SARS-CoV-2 Testing	Local test	83.00	1.0	83		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Bortezomib Administration	IV/SC administration	95.00	36.0	3420		1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		0.00		0.00		0.00	
	Includes: Distribute emergency contact card, Infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check																																			
Study Coordinator Fee		37.00	133.3	4930.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	1.50	55.50	1.50	55.50
Admin/Data Entry Fee		31.00	41.0	1271	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	0.50	15.50	0.50	15.50		
BMA for MRD, Molecular Profiling	Sample collection	232.00	1.0	232		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
BMB for protein profiling	Sample collection	314.00	1.0	314		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Pharmacy Fee	Oral Drug prep and dispense	32.00	10.0	320		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00		1.00	32.00		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00	
Pharmacy Fee	IV drug prep and dispense	45.00	36.0	1620		1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00		0.00		0.00		0.00	
Body Surface Area calculation		17.00	36.0	612		1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00		0.00		0.00		0.00		0.00	
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114.00	1.0	114		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
CMV PCR		42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
EBV PCR		58.00	1.0	58		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Adenovirus PCR		46.00	1.0	46		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
			0.0	0		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
	PSC Subtotal w/out Overhead			16,660.25		308.25		308.25		308.25		548.50		308.25		308.25		308.25		548.50		308.25		548.50		308.25		466.25		312.25		71.00		109.00		
	PSC Subtotal with Overhead			19,325.89		357.57		357.57		357.57		636.26		357.57		357.57		357.57		636.26		357.57		636.26		357.57		540.85		362.21		82.36		126.44		

Additional Procedures that may not apply to all Patients					f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D11	f	C2D1	f	C2D4	f	C2D8	f	C2D11	f	C3D1	f	C3D4	f	C3D8	f	C3D11
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	1,0	19	1,00	19,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	1,0	27	1,00	27,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00	1,00	58,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00	1,00	46,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.660,25		1.602,25		688,50		346,25		346,25		346,25		548,50		346,25		346,25		346,25		548,50		308,25		308,25		308,25
Additional Cost Subtotal				3.982,00		2.450,00		277,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00
Subtotal				20.642,25		4.052,25		965,50		346,25		346,25		346,25		679,50		346,25		346,25		346,25		679,50		308,25		308,25		308,25
Overhead				3.302,76		648,36		154,48		55,40		55,40		55,40		108,72		55,40		55,40		55,40		108,72		49,32		49,32		49,32
INVESTIGATOR COST PER SUBJECT with Overhead				23.945,01		4.700,61		1.119,98		401,65		401,65		401,65		788,22		401,65		401,65		401,65		788,22		357,57		357,57		357,57

Additional Procedures that may not apply to all Patients					f	C4D1	f	C4D4	f	C4D8	f	C4D11	f	C5D1	f	C5D4	f	C5D8	f	C5D11	f	C6D1	f	C6D4	f	C6D8	f	C6D11	f	C7D1
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	1,0	19		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	1,0	27		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.660,25		664,50		308,25		308,25		308,25		548,50		308,25		308,25		308,25		664,50		308,25		308,25		308,25		548,50
Additional Cost Subtotal				3.982,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00
Subtotal				20.642,25		795,50		308,25		308,25		308,25		679,50		308,25		308,25		308,25		795,50		308,25		308,25		308,25		679,50
Overhead				3.302,76		127,28		49,32		49,32		49,32		108,72		49,32		49,32		49,32		127,28		49,32		49,32		49,32		108,72
INVESTIGATOR COST PER SUBJECT with Overhead				23.945,01		922,78		357,57		357,57		357,57		788,22		357,57		357,57		357,57		922,78		357,57		357,57		357,57		788,22

Additional Procedures that may not apply to all Patients					f	C7D4	f	C7D8	f	C7D11	f	C8D1	f	C8D4	f	C8D8	f	C8D11	f	C9D1	f	C9D8	f	C10D1	f	C10D8	f	EOT	f	FU	f	LTFU	f	LTD4
ECHO	Either Echo or MUGA	740.00	1.0	740		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
MUGA	Either Echo or MUGA	618.00	1.0	618		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162.00	1.0	162		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753.00	1.0	753		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38.00	2.0	76		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	38.00	1.00	38.00		0.00
Urine Pregnancy Test	WOCBP only	19.00	1.0	19		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Serum Pregnancy Test	WOCBP only	27.00	1.0	27		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 PCR		71.00	11.0	781		0.00		0.00		0.00	1.00	71.00		0.00		0.00		0.00	1.00	71.00		0.00	1.00	71.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 Antigen		60.00	11.0	660		0.00		0.00		0.00	1.00	60.00		0.00		0.00		0.00	1.00	60.00		0.00	1.00	60.00		0.00		0.00		0.00		0.00		0.00
CMV PCR	If screening test performed >7 days	42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
EBV PCR	If screening test performed >7 days	58.00	1.0	58		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Adenovirus PCR	If screening test performed >7 days	46.00	1.0	46		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal				16,660.25		308.25		308.25		308.25		548.50		308.25		308.25		308.25		548.50		308.25		548.50		308.25		466.25		312.25		71.00		109.00
Additional Cost Subtotal				3,982.00		0.00		0.00		0.00		131.00		0.00		0.00		0.00		131.00		0.00		131.00		0.00		0.00		38.00		38.00		0.00
Subtotal				20,642.25		308.25		308.25		308.25		679.50		308.25		308.25		308.25		679.50		308.25		679.50		308.25		466.25		350.25		109.00		109.00
Overhead				3,302.76		49.32		49.32		49.32		108.72		49.32		49.32		49.32		108.72		49.32		108.72		49.32		74.60		56.04		17.44		17.44
INVESTIGATOR COST PER SUBJECT with Overhead				23,945.01		357.57		357.57		357.57		788.22		357.57		357.57		357.57		788.22		357.57		788.22		357.57		540.85		406.29		126.44		126.44

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	1,201.69
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	28.00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	24.00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873.48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1,052.12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870.00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992.96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1,375.76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1,126.36

MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
Triplicate 12 Lead ECG	As clinically indicated	83,52
Unscheduled Visit	Includes 1 HR of SC and 1 HR DE time	78,88
Anesthesia for BMA or BMB		316,68
BMB for protein profiling	Sample collection	269,12
BMA for MRD, Molecular Profiling	Sample collection	364,24
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting		37,00
SAE	Includes all reports and follow up	63,00
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally/ additional testing required	114,84
CMV PCR	If additional testing required	48,72
EBV PCR	If additional testing required	67,28
Adenovirus PCR	If additional testing required	53,36
Additional LTFU	Paid based on EDC completion	82,36
Additional LTDA	Paid based on EDC completion	126,44
Additional Cycles - D1	Paid based on EDC completion	636,26

Additional Cycles - D8	Paid based on EDC completion	357,57
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68

ARM B (KD)

COMPOUND :	Elranatamab	AMENDMENT :	PA3	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B(KD)	INSTITUTION:	AOU P. Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.			CCID:	1031
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13		VISIT 14			
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Screening	f	C1D1	f	C1D2	f	C1D8	f	C1D9	f	C1D15	f	C1D16	f	C1D22	f	C2D1	f	C2D2	f	C2D8	f	C2D9	f	C2D15	f	C2D16		
Informed Consent		43.00	1.0	43	1.00	43.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75.00	1.0	75	1.00	75.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	5.0	100	1.00	20.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	1.00	155.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	9.0	648		0.00	1.00	72.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00		0.00		0.00		
Full Neurologic Exam		82.00	1.0	82	1.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Targeted Neurologic Exam		69.00	12.0	828		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		
ECOG PS		20.00	1.0	20	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	1.00	61.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00	1.00	116.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		
	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for ctDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)																																	
Central Lab - includes collection, processing and shipping		38.00	21.0	798	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00		0.00	1.00	38.00		0.00	1.00	38.00	1.00	38.00		0.00	1.00	38.00		0.00	1.00	38.00		0.00		
Saliva sample for germline comparator		24.00	1.0	24		0.00	1.00	24.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
SARS-CoV-2 Testing	Local test	83.00	1.0	83	1.00	83.00				0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
			0.0	0		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check																																	
Study Coordinator Fee		37.00	155.3	5744.25	4.25	157.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25		0.00	3.25	120.25	3.25	120.25		
Admin/Data Entry Fee		31.00	49.0	1519	2.00	62.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00		
Carfilzomib Administration	IV administration	95.00	41.0	3895		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		0.00	1.00	95.00		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		
Pharmacy Fee	IV drug prep and dispense	45.00	41.0	1845		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		
Pharmacy Fee	Oral Drug prep and dispense	32.00	7.0	224		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00		
BMB for protein profiling	Sample collection	314.00	1.0	314	1.00	314.00				0.00		0.00		0.00		0.00		0.00		0.00				0.00		0.00		0.00		0.00		0.00		
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling	Fee includes HBsAg, HbCAb and HBsAb	232.00	1.0	232	1.00	232.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
HBV testing		114.00	1.0	114	1.00	114.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
CMV PCR		42.00	1.0	42	1.00	42.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
EBV PCR		58.00	1.0	58	1.00	58.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
Adenovirus PCR		46.00	1.0	46	1.00	46.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		
				PSC Subtotal w/out Overhead																														
						17,646.25		1,602.25		671.50		329.25		329.25		291.25		534.25		291.25		189.25		511.50		151.25		329.25		171.00		514.25		291.25
				PSC Subtotal with Overhead																														
						20,469.65		1,858.61		778.94		381.93		381.93		337.85		619.73		337.85		219.53		593.34		175.45		381.93		198.36		596.53		337.85

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		VISIT 27		
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C2D22	f	C3D1	f	C3D2	f	C3D8	f	C3D9	f	C3D15	f	C3D16	f	C4D1	f	C4D2	f	C4D8	f	C4D9	f	C4D15	f	C4D16	
Informed Consent		43.00	1.0	43		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75.00	1.0	75		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	5.0	100		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	9.0	648		0.00	1.00	72.00		0.00		0.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00		0.00		0.00	
Full Neurologic Exam		82.00	1.0	82		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Targeted Neurologic Exam		69.00	12.0	828		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00		0.00		0.00		0.00		0.00	
ECOG PS		20.00	1.0	20		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00		0.00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38.00	21.0	798	1.00	38.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00	
	Saliva sample for germline comparator	24.00	1.0	24		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
	SARS-CoV-2 Testing	83.00	1.0	83		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
	Local test			0.0	0		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37.00	155.3	5744.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	
	Admin/Data Entry Fee	31.00	49.0	1519	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	
	Carfilzomib Administration	95.00	41.0	3895		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	
	Pharmacy Fee	45.00	41.0	1845		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	
	Pharmacy Fee	32.00	7.0	224		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00	
	BMB for protein profiling	Sample collection	314.00	1.0	314		0.00				0.00		0.00		0.00		0.00		0.00				0.00		0.00		0.00		0.00		0.00
	BMA for MRD, disease assessment, cytogenetics and Molecular Profiling	Fee includes HBSAg, HBCAb and HBsAb	232.00	1.0	232		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	HBV testing		114.00	1.0	114		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	CMV PCR		42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	EBV PCR		58.00	1.0	58		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Adenovirus PCR		46.00	1.0	46		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	
				PSC Subtotal w/out Overhead																											
				17,646.25		189.25		511.50		291.25		291.25		291.25		398.25		291.25		627.50		291.25		291.25		291.25		329.25		291.25	
				PSC Subtotal with Overhead																											
				20,469.65		219.53		593.34		337.85		337.85		337.85		461.97		337.85		727.90		337.85		337.85		337.85		381.93		337.85	

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 28		VISIT 29		VISIT 30		VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36		VISIT 37		VISIT 38		VISIT 39		VISIT 40		VISIT 41	
					f	CSD1	f	CSD2	f	CSD8	f	CSD9	f	CSD15	f	CSD16	f	C6D1	f	C6D2	f	C6D8	f	C6D9	f	C6D15	f	C6D16	f	C7D1	f	C7D2
Informed Consent		43.00	1.0	43	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75.00	1.0	75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-SL, WPAI and PGIC	20.00	5.0	100	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	9.0	648	1.00	72.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	72.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	72.00	0.00		
Full Neurologic Exam		82.00	1.0	82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Targeted Neurologic Exam		69.00	12.0	828	1.00	69.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	69.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	69.00	0.00	0.00		
ECOG PS		20.00	1.0	20	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	116.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)																															
		38.00	21.0	798	1.00	38.00	0.00	0.00	0.00	0.00	0.00	1.00	38.00	0.00	0.00	1.00	38.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	38.00	0.00	1.00	38.00	0.00		
	Saliva sample for germline comparator	24.00	1.0	24	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
	SARS-CoV-2 Testing	Local test	83.00	1.0	83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			0.0	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37.00	155.3	5744.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25
Admin/Data Entry Fee		31.00	49.0	1519	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	
Carfilzomib Administration	IV administration	95.00	41.0	3895	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	
Pharmacy Fee	IV drug prep and dispense	45.00	41.0	1845	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	
Pharmacy Fee	Oral Drug prep and dispense	32.00	7.0	224	1.00	32.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	32.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	32.00	0.00		
BMB for protein profiling	Sample collection	314.00	1.0	314	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling	Fee includes HBsAg, HbcAb and HBsAb	232.00	1.0	232	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
HBV testing		114.00	1.0	114	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
CMV PCR		42.00	1.0	42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
EBV PCR		58.00	1.0	58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Adenovirus PCR		46.00	1.0	46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
	PSC Subtotal w/out Overhead																															
				17,646.25	511.50	291.25	291.25	291.25	291.25	329.25	291.25	627.50	291.25	291.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	329.25	291.25	
	PSC Subtotal with Overhead			20,469.65	593.34	337.85	337.85	337.85	337.85	381.93	337.85	727.90	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	337.85	593.34	337.85	337.85	

DESCRIPTION OF COST	Comments	Frequency of Procedure		VISIT 42		VISIT 43		VISIT 44		VISIT 45		VISIT 46		VISIT 47		VISIT 48		VISIT 49		
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C7D8	f	C7D9	f	C7D15	f	C7D16	f	EOT	f	FU	f	LTFU	f	LTD A
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History		75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	5,0	100		0,00		0,00		0,00		0,00	1,00	20,00	1,00	20,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	9,0	648		0,00		0,00		0,00		0,00	1,00	72,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00		0,00		0,00		0,00	1,00	69,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
TriPLICATE 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38,00	21,0	798		0,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00	1,00	38,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0		0		0		0
			0,0	0		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37,00	155,3	5744,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	1,50	55,50	1,50	55,50
Admin/Data Entry Fee		31,00	49,0	1519	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	0,50	15,50	0,50	15,50
Carfilizomb Administration	IV administration	95,00	41,0	3895	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00		0,00
Pharmacy Fee	IV drug prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00		0,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	7,0	224		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling	Fee includes HBsAg, HBcAb and HBsAb	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing		114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR		58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR		46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			17.646,25		291,25		291,25		291,25		291,25		466,25		312,25		71,00		109,00
	PSC Subtotal with Overhead			20.469,65		337,85		337,85		337,85		337,85		540,85		362,21		82,36		126,44

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D2	f	C1D8	f	C1D9	f	C1D15	f	C1D16	f	C1D22	f	C2D1	f	C2D2	f	C2D8	f	C2D9	f	C2D15	f	C2D16
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for Protein profiling	Optional collection	232,00	1,0	232	1,00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	8,0	152	1,00	19,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	8,0	216	1,00	27,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	8,0	568	1,00	71,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	8,0	480	1,00	60,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00	1,00	58,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00	1,00	46,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				17.646,25		1.602,25		671,50		329,25		329,25		291,25		534,25		291,25		189,25		511,50		151,25		329,25		171,00		514,25		291,25
Additional Cost Subtotal				4.143,00		2.682,00		323,00		0,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00
Subtotal				21.789,25		4.284,25		994,50		329,25		329,25		291,25		534,25		291,25		189,25		688,50		151,25		329,25		171,00		514,25		291,25
Overhead				3.486,28		685,48		159,12		52,68		52,68		46,60		85,48		46,60		30,28		110,16		24,20		52,68		27,36		82,28		46,60
INVESTIGATOR COST PER SUBJECT with Overhead				25.275,53		4.969,73		1.153,62		381,93		381,93		337,85		619,73		337,85		219,53		798,66		175,45		381,93		198,36		596,53		337,85

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D22	f	C3D1	f	C3D2	f	C3D8	f	C3D9	f	C3D15	f	C3D16	f	C4D1	f	C4D2	f	C4D8	f	C4D9	f	C4D15	f	C4D16
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	8,0	152		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	8,0	216		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	8,0	568		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	8,0	480		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				17.646,25		189,25		511,50		291,25		291,25		291,25		398,25		291,25		627,50		291,25		291,25		291,25		329,25		291,25
Additional Cost Subtotal				4.143,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00
Subtotal				21.789,25		189,25		688,50		291,25		291,25		291,25		398,25		291,25		804,50		291,25		291,25		291,25		329,25		291,25
Overhead				3.486,28		30,28		110,16		46,60		46,60		46,60		63,72		46,60		128,72		46,60		46,60		46,60		52,68		46,60
INVESTIGATOR COST PER SUBJECT with Overhead				25.275,53		219,53		798,66		337,85		337,85		337,85		461,97		337,85		933,22		337,85		337,85		337,85		381,93		337,85

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D1	f	C5D2	f	C5D8	f	C5D9	f	C5D15	f	C5D16	f	C6D1	f	C6D2	f	C6D8	f	C6D9	f	C6D15	f	C6D16	f	C7D1	f	C7D2
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	8,0	152	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	8,0	216	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00
SARS-CoV-2 PCR		71,00	8,0	568	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00
SARS-CoV-2 Antigen		60,00	8,0	480	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				17.646,25		511,50		291,25		291,25		291,25		329,25		291,25		627,50		291,25		291,25		291,25		329,25		291,25		511,50		291,25
Additional Cost Subtotal				4.143,00		177,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00
Subtotal				21.789,25		688,50		291,25		291,25		291,25		329,25		291,25		804,50		291,25		291,25		291,25		329,25		291,25		688,50		291,25
Overhead				3.486,28		110,16		46,60		46,60		46,60		52,68		46,60		128,72		46,60		46,60		46,60		52,68		46,60		110,16		46,60
INVESTIGATOR COST PER SUBJECT with Overhead				25.275,53		798,66		337,85		337,85		337,85		381,93		337,85		933,22		337,85		337,85		337,85		381,93		337,85		798,66		337,85

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C7D8	f	C7D9	f	C7D15	f	C7D16	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	8,0	152		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	8,0	216		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	8,0	568		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	8,0	480		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
EBV PCR	If screening test performed >7 days	58,00	1,0	58		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Adenovirus PCR	If screening test performed >7 days	46,00	1,0	46		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				17.646,25		291,25		291,25		291,25		291,25		466,25		312,25		71,00		109,00
Additional Cost Subtotal				4.143,00		0,00		0,00		0,00		0,00		0,00		38,00		38,00		0,00
Subtotal				21.789,25		291,25		291,25		291,25		291,25		466,25		350,25		109,00		109,00
Overhead				3.486,28		46,60		46,60		46,60		46,60		74,60		56,04		17,44		17,44
INVESTIGATOR COST PER SUBJECT with Overhead				25.275,53		337,85		337,85		337,85		337,85		540,85		406,29		126,44		126,44

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	1.201,69
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	28,00
Subject/Caregiver Meal Reimbursement	Per meal/onsite visit only, reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36

BMA for disease assessment	Sample Collection Additional timepoints	269,12
Unscheduled Visit	Includes 1hr SC and 1hr DE time. Invoice for other activities completed	78,88
Anesthesia for BMA or BMB		316,68
Dry Ice	Per shipment	18,00
Triplicate 12 Lead ECG	As clinically indicated	134,56
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting		37,00
SAE	Includes all reports and follow up	63,00
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If local/ additional testing required	114,84
CMV PCR	If additional testing required	48,72
EBV PCR	If additional testing required	67,28
Adenovirus PCR	If additional testing required	53,36
Additional LTFU	Paid based on EDC completion	82,36
Additional LTDA	Paid based on EDC completion	126,44
Additional cycles - D1	Additional cycles past C7 - Paid based on EDC entry	593,34
Additional cycles - D2	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D8	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D9	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D15	Additional cycles past C7 - Paid based on EDC entry	337,85
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	269,12
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Additional cycles - D16	Additional cycles past C7 - Paid based on EDC entry	337,85

Exhibit 1 – Annex A/ Appendice 1 - Allegato A -PA4

ARM A -PER SUBJECT COST:

COMPOUND :	Elranatamab	AMENDMENT :	PA4	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm A	INSTITUTION:	AOU Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.			CCID:	1031
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22
Informed Consent		43.00	1.0	43	1.00	43.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75	1.00	75.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	16.0	320	1.00	20.00	1.00	20.00		0.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	1.00	155.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864		0.00	1.00	72.00		0.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00
Full Neurologic Exam		82.00	1.0	82	1.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Neurologic Exam		69.00	15.0	1035		0.00	1.00	69.00		0.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00	1.00	69.00		0.00
ECOG PS		20.00	1.0	20	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	1.00	61.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00	1.00	116.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00	1.00	116.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B), PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38.00	18.0	684	1.00	38.00	1.00	38.00		0.00	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00		0.00	1.00	38.00		0.00
	comparator	24.00	1.0	24		0.00	1.00	24.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	SARS-CoV-2 testing	83.00	1.0	83	1.00	83.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	Elrantamab administration	28.00	41.0	1148		0.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
	Pharmacy Fee - IV Premedication /SC elrantamab PK	Prep and dispense	45.00	41.0	1845		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00
		24.00	11.0	264		0.00	2.00	48.00	2.00	48.00	1.00	24.00		0.00		0.00	1.00	24.00		0.00		0.00		0.00
	Includes: Distribute emergency contact card, infection reminder card and CRS/ICANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37.00	149.5	5531.5	4.25	157.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25
Admin/Data Entry Fee		31.00	90.0	2790	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00
BMB for protein profiling	Sample collection	314.00	1.0	314	1.00	314.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114.00	1.0	114	1.00	114.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR		42.00	1.0	42	1.00	42.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	PSC Subtotal w/out Overhead					16,190.50		1,266.25		651.50		303.25		317.25		498.25		293.25		487.50		255.25		498.25
	PSC Subtotal with Overhead					18,780.98		1,468.85		755.74		351.77		368.01		577.97		340.17		565.50		296.09		577.97

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 11		VISIT 12		VISIT 13		VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C3D1	f	C3D8	f	C3D15	f	C3D22	f	C4D1	f	C4D8	f	C4D15	f	C4D22	f	C5D1	f	C5D8
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	16,0	320	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38,00	18,0	684	1,00	38,00		0,00	1,00	38,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00
comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elranatamab administration	SC injection	28,00	41,0	1148	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00
Pharmacy Fee - IV Premedication /SC elranatamab PK	Prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
		24,00	11,0	264	1,00	24,00		0,00		0,00		0,00	1,00	24,00		0,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/CAUS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	149,5	5531,5	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25
Admin/Data Entry Fee		31,00	90,0	2790	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114		0,00				0,00		0,00		0,00				0,00		0,00		0,00		
CMV PCR		42,00	1,0	42		0,00				0,00		0,00		0,00				0,00		0,00		0,00		
				PSC Subtotal w/out Overhead																				
				16.190,50		487,50		255,25		382,25		255,25		603,50		255,25		255,25		255,25		463,50		255,25
				18.780,98		565,50		296,09		443,41		296,09		700,06		296,09		296,09		296,09		537,66		296,09

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31	
					f	C5D15	f	C5D22	f	C6D1	f	C6D8	f	C6D15	f	C6D22	f	C7D1	f	C7D8	f	C7D15	f	C7D22	f	C8D1
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	16,0	320		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00	1,00	116,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38,00	18,0	684		0,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00
comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elranatamab administration	SC injection	28,00	41,0	1148	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00	1,00	28,00
Pharmacy Fee - IV Premedication /SC elranatamab PK	Prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
		24,00	11,0	264		0,00		0,00		0,00		0,00		0,00		0,00	1,00	24,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/CANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	149,5	5531,5	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50
Admin/Data Entry Fee		31,00	90,0	2790	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
				PSC Subtotal w/out Overhead																						
				16.190,50		255,25		255,25		579,50		255,25		255,25		255,25		487,50		255,25		255,25		255,25		463,50
				18.780,98		296,09		296,09		672,22		296,09		296,09		296,09		565,50		296,09		296,09		296,09		537,66

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36		VISIT 37		VISIT 38		VISIT 39		VISIT 40		VISIT 41		VISIT 42		VISIT 43		VISIT 44		VISIT 45		VISIT 46	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C8D8	f	C8D15	f	C8D22	f	C9D1	f	C9D8	f	C9D15	f	C9D22	f	C10D1	f	C10D8	f	C10D15	f	C10D22	f	EOT	f	FU	f	LTFU	f	LTDA
formed Consent		43.00	1.0	43		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
30s	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	16.0	320		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00	1.00	20.00		0.00		0.00
# Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
urgeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00	1.00	72.00		0.00		0.00
# Neurologic Exam		82.00	1.0	82		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
urgeted Neurologic Exam		69.00	15.0	1035		0.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00	1.00	69.00		0.00		0.00
OG PS		20.00	1.0	20		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
ngle 12 Lead ECG	Includes interpretation and report	61.00	1.0	61		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
iplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B), PT/INR, Blood sample for sBCMA levels, Blood sample for ctDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38.00	18.0	684		0.00		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00		0.00	1.00	38.00
comparator		24.00	1.0	24		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
VRS-CoV-2 testing	Local test	83.00	1.0	83		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
rantamab administration	SC injection	28.00	41.0	1148	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00		0.00		0.00
Premedication/SC elranatamab	Prep and dispense	45.00	41.0	1845	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00		0.00		0.00
elranatamab PK		24.00	11.0	264		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	24.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
udy Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card and CRS/CANS reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37.00	149.5	5531.5	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	1.50	55.50	1.50	55.50
IminData Entry Fee		31.00	90.0	2790	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	1.00	31.00	1.00	31.00
VB for protein profiling	Sample collection	314.00	1.0	314		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
3V testing	Fee includes HBsAg, HBcAb and HBsAb	114.00	1.0	114				0.00				0.00				0.00				0.00				0.00				0.00		0.00		0.00		0.00
IV PCR		42.00	1.0	42				0.00				0.00				0.00				0.00				0.00				0.00		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			16,190.50		255.25		255.25		255.25		463.50		255.25		255.25		255.25		487.50		255.25		255.25		255.25		521.25		343.25		86.50		124.50
	PSC Subtotal with Overhead			18,780.98		296.09		296.09		296.09		537.66		296.09		296.09		296.09		565.50		296.09		296.09		296.09		604.65		398.17		100.34		144.42

ARM A- ADDITIONAL TREATMENT RELATED COSTS

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elarantamab	IV administration Refer to Table 5	95,00	3,0	285		0,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39	1,00	39,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE). Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00	1,00	38,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00	2,00	1.400,00	1,00	700,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304	1,00	19,00	1,00	19,00		0,00	1,00	19,00	1,00	19,00	1,00	19,00	1,00	19,00		0,00		0,00		0,00	1,00	19,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432	1,00	27,00	1,00	27,00		0,00	1,00	27,00	1,00	27,00	1,00	27,00	1,00	27,00		0,00		0,00		0,00	1,00	27,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00	1,00	71,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00	1,00	60,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used	232,00	1,0	232	1,00	232,00				0,00		0,00		0,00		0,00				0,00		0,00		0,00		
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.190,50		1.266,25		651,50		303,25		317,25		498,25		293,25		487,50		255,25		498,25		255,25		487,50
Additional Cost Subtotal				7.262,00		2.721,00		1.714,00		833,00		141,00		46,00		46,00		177,00		0,00		0,00		0,00		177,00
Subtotal				23.452,50		3.987,25		2.365,50		1.136,25		458,25		544,25		339,25		664,50		255,25		498,25		255,25		664,50
Overhead				3.752,40		637,96		378,48		181,80		73,32		87,08		54,28		106,32		40,84		79,72		40,84		106,32
INVESTIGATOR COST PER SUBJECT with Overhead				27.204,90		4.625,21		2.743,98		1.318,05		531,57		631,33		393,53		770,82		296,09		577,97		296,09		770,82

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C3D8	f	C3D15	f	C3D22	f	C4D1	f	C4D8	f	C4D15	f	C4D22	f	C5D1	f	C5D8	f	C5D15	f	C5D22
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elrantomab	IV administration Refer to Table 5	95,00	3,0	285		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used	232,00	1,0	232		0,00		0,00		0,00				0,00		0,00		0,00				0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.190,50		255,25		382,25		255,25		603,50		255,25		255,25		255,25		463,50		255,25		255,25		255,25
Additional Cost Subtotal				7.262,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00
Subtotal				23.452,50		255,25		382,25		255,25		780,50		255,25		255,25		255,25		640,50		255,25		255,25		255,25
Overhead				3.752,40		40,84		61,16		40,84		124,88		40,84		40,84		40,84		102,48		40,84		40,84		40,84
INVESTIGATOR COST PER SUBJECT with Overhead				27.204,90		296,09		443,41		296,09		905,38		296,09		296,09		296,09		742,98		296,09		296,09		296,09

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C6D1	f	C6D8	f	C6D15	f	C6D22	f	C7D1	f	C7D8	f	C7D15	f	C7D22	f	C8D1	f	C8D8	f	C8D15
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Administration of premedication for elrantomab	IV administration Refer to Table 5	95,00	3,0	285		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,	38,00	3,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4	700,00	3,0	2100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	16,0	304	1,00	19,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	16,0	432	1,00	27,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used	232,00	1,0	232				0,00		0,00		0,00				0,00		0,00		0,00				0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.190,50		579,50		255,25		255,25		255,25		487,50		255,25		255,25		255,25		463,50		255,25		255,25
Additional Cost Subtotal				7.262,00		177,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		177,00		0,00		0,00
Subtotal				23.452,50		756,50		255,25		255,25		255,25		664,50		255,25		255,25		255,25		640,50		255,25		255,25
Overhead				3.752,40		121,04		40,84		40,84		40,84		106,32		40,84		40,84		40,84		102,48		40,84		40,84
INVESTIGATOR COST PER SUBJECT with Overhead				27.204,90		877,54		296,09		296,09		296,09		770,82		296,09		296,09		296,09		742,98		296,09		296,09

Additional Procedures that may not apply to all Patients			COST	Total Number of times a procedure may occur	Total Potential PSC	f	C8D22	f	C9D1	f	C9D8	f	C9D15	f	C9D22	f	C10D1	f	C10D8	f	C10D15	f	C10D22	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA		740.00	1.0	740		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
MUGA	Either Echo or MUGA		618.00	1.0	618		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both		162.00	1.0	162		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both		753.00	1.0	753		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Administration of premedication for elrantomab	IV administration Refer to Table 5		95.00	3.0	285		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone		39.00	1.0	39		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Hematology and serum sample for circulating proteins and/or metabolite analysis,		38.00	3.0	114		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	38.00	1.00	38.00		0.00
Hospital Stay	C1D1; Optional 24 hour stay for C1D4		700.00	3.0	2100		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Urine Pregnancy Test	WOCBP only		19.00	16.0	304		0.00	1.00	19.00		0.00		0.00		0.00	1.00	19.00		0.00		0.00		0.00	1.00	19.00	1.00	19.00		0.00		0.00
Serum Pregnancy Test	WOCBP only		27.00	16.0	432		0.00	1.00	27.00		0.00		0.00		0.00	1.00	27.00		0.00		0.00		0.00	1.00	27.00	1.00	27.00		0.00		0.00
SARS-CoV-2 PCR			71.00	11.0	781		0.00	1.00	71.00		0.00		0.00		0.00	1.00	71.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 Antigen			60.00	11.0	660		0.00	1.00	60.00		0.00		0.00		0.00	1.00	60.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used		232.00	1.0	232		0.00				0.00		0.00		0.00				0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR	If screening test performed >7 days		42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal					16,190.50		255.25		463.50		255.25		255.25		255.25		487.50		255.25		255.25		255.25		521.25		343.25		86.50		124.50
Additional Cost Subtotal					7,262.00		0.00		177.00		0.00		0.00		0.00		177.00		0.00		0.00		0.00		46.00		84.00		38.00		0.00
Subtotal					23,452.50		255.25		640.50		255.25		255.25		255.25		664.50		255.25		255.25		255.25		567.25		427.25		124.50		124.50
Overhead					3,752.40		40.84		102.48		40.84		40.84		40.84		106.32		40.84		40.84		40.84		90.76		68.36		19.92		19.92
INVESTIGATOR COST PER SUBJECT with Overhead					27,204.90		296.09		742.98		296.09		296.09		296.09		770.82		296.09		296.09		296.09		658.01		495.61		144.42		144.42

ARM A- Other costs

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Pharmacy start-up fee	Invoice once at start up	697,00
Admin start-up fee	Invoice once at start up	1.727,00
Record Archiving	Invoice once at study close	2.564,00
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	949,69
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	28,00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
BMA for disease assessment	Sample collection	269,12
Unscheduled Visit	Includes 1Hr SC and 1 Hr DE time	78,88
Anesthesia for BMA or BMB	Invoice as incurred	316,68
Triplicate 12 Lead ECG	Invoice as incurred	134,56
Additional LTFU	Paid based on EDC completion,	100,34
Additional LTDA	Paid based on EDC completion,	144,42
Additional Cycles - D1	Paid based on EDC completion,	565,50
Additional Cycles - D8	Paid based on EDC completion,	296,09
Additional Cycles - D15	Paid based on EDC completion,	296,09
Additional Cycles - D22	Paid based on EDC completion,	296,09

PROs	Invoice as incurred > C10 Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC,	23,20
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed.	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally,	114,84
CMV PCR	If required locally	48,72
Immunoglobulin replacement IVIG (SC administration)	Invoice as incurred	32,48
Immunoglobulin replacement IVIG (IV administration)	Invoice as incurred	110,20
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If required locally	69,60
Reconsenting	Invoice as incurred	37,00
SAE	Includes all reports and follow up	63,00
Pharmacy Close out	Invoice at study close	335,00
Plasma Cells % - local analysis	To be invoiced as incurred.	23,20
Kappa Light Chain - local analysis	To be invoiced as incurred.	32,48
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Lambda Light Chain - local analysis	To be invoiced as incurred.	32,48

ARM B(EPD) -PER SUBJECT COST

COMPOUND :	Elranatamab	AMENDMENT :	PA4	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B(Epd)	INSTITUTION:	AOU P.Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (PVd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.			CCID:	1031
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13	
					f	Screening	f	C1D1	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1	f	C3D15	f	C4D1	f	C4D15
Informed Consent		43,00	1,0	43	1,00	43,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75	1,00	75,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAl and PSIC	20,00	16,0	320	1,00	20,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00	1,00	20,00	1,00	20,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155	1,00	155,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00	1,00	72,00		0,00
Full Neurologic Exam		82,00	1,0	82	1,00	82,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00	1,00	69,00	1,00	69,00		0,00
ECOG PS		20,00	1,0	20	1,00	20,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61	1,00	61,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00	1,00	116,00		0,00	1,00	116,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00	1,00	116,00		0,00	1,00	116,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B], PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and NAb's against elranatamab (Arm A)	38,00	18,0	684	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	0,00	0,00	1,00	38,00	0,00	0,00	1,00	38,00	1,00	38,00	1,00	38,00	0,00	0,00
Saliva sample for germline comparator		24,00	1,0	24		0,00	1,00	24,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1,0	83	1,00	83,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elotuzumab administration	ARM B - IV administration	95,00	16,0	1520		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00
Pharmacy Fee-Elotuzumab	ARM B - Elotuzumab Prep and dispense	45,00	16,0	720		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00
Pharmacy Fee - Oral	Oral Drug dispense	32,00	16,0	512		0,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00		0,00
Administration of premedication for elotuzumab	if administered IV - Arm B. Refer to table 5	95,00	16,0	1520		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00
Pharmacy Fee - Premedication for elotuzumab	ARM B - Prep and dispense IV drug	45,00	16,0	720		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00	1,00	45,00		0,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	81,3	3006,25	4,25	157,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,50	129,50	3,25	120,25
Admin/Data Entry Fee		31,00	48,0	1488	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00		62,00
BMB for protein profiling	Sample collection	314,00	1,0	314	1,00	314,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114	1,00	114,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			14.098,25		1.266,25		842,50		532,25		737,25		532,25		702,50		494,25		737,25		494,25		702,50		309,25		818,50		182,25
	PSC Subtotal with Overhead			16.353,97		1.468,85		977,30		617,41		855,21		617,41		814,90		573,33		855,21		573,33		814,90		358,73		949,46		211,41

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25	
					f	C5D1	f	C5D15	f	C6D1	f	C6D15	f	C7D1	f	C8D1	f	C9D1	f	C10D1	f	EOT	f	FU	f	LTFU	f	LTDA
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	16,0	320	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00	1,00	20,00	1,00	20,00	1,00	20,00	1,00	20,00	1,00	20,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864	1,00	72,00		0,00	1,00	72,00		0,00	1,00	72,00	1,00	72,00	1,00	72,00	1,00	72,00	1,00	72,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	15,0	1035	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00	1,00	69,00	1,00	69,00	1,00	69,00	1,00	69,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00	1,00	116,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative Immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, TSH and reflex testing (T3 and free T4) Arm B), PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), Blood sample for ADA's and Nabs against elranatamab (Arm A)	38,00	18,0	684	1,00	38,00	0,00	0,00	1,00	38,00	0,00	0,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00		0,00		0,00	1,00	38,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Elotuzumab administration	ARM B - IV administration	95,00	16,0	1520	1,00	95,00		0,00	1,00	95,00		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00
Pharmacy Fee-Elotuzumab	ARM B - Elotuzumab Prep and dispense	45,00	16,0	720	1,00	45,00		0,00	1,00	45,00		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00
Pharmacy Fee - Oral	Oral Drug dispense	32,00	16,0	512	1,00	32,00		0,00	1,00	32,00		0,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00	1,00	32,00		0,00		0,00		0,00
Administration of premedication for elotuzumab	If administered IV - Arm B Refer to table 5	95,00	16,0	1520	1,00	95,00		0,00	1,00	95,00		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00		0,00
Pharmacy Fee - Premedication for elotuzumab	ARM B - Prep and dispense IV drug	45,00	16,0	720	1,00	45,00		0,00	1,00	45,00		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check,	37,00	81,3	3006,25	3,50	129,50	3,25	120,25	3,50	129,50	3,25	120,25	3,50	129,50	3,50	129,50	3,50	129,50	3,50	129,50	3,25	120,25	3,25	120,25	1,50	55,50	1,50	55,50
Admin/Data Entry Fee		31,00	48,0	1488	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	2,00	62,00	1,00	31,00	1,00	31,00
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBCAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
				PSC Subtotal w/out Overhead																								
				14,098,25		702,50		182,25		818,50		182,25		702,50		702,50		702,50		702,50		497,25		343,25		86,50		124,50
				PSC Subtotal with Overhead																								
				16,353,97		814,90		211,41		949,46		211,41		814,90		814,90		814,90		814,90		576,81		398,17		100,34		144,42

ARM B (EPD) -ADDITIONAL TREATMENT RELATED COSTS

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D8	f	C1D15	f	C1D22	f	C2D1	f	C2D8	f	C2D15	f	C2D22	f	C3D1	f	C3D15	f	C4D1	f	C4D15
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39	1,00	39,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76				0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	11,0	209	1,00	19,00	1,00	19,00	0,00	0,00	0,00	0,00	0,00	0,00	1,00	19,00	0,00	0,00	0,00	0,00	0,00	1,00	19,00	0,00	0,00	1,00	19,00	0,00	0,00	0,00
Serum Pregnancy Test	WOCBP only	27,00	11,0	297	1,00	27,00	1,00	27,00	0,00	0,00	0,00	0,00	0,00	0,00	1,00	27,00	0,00	0,00	0,00	0,00	0,00	1,00	27,00	0,00	0,00	1,00	27,00	0,00	0,00	0,00
SARS-CoV-2 PCR		71,00	1,0	71			0,00	1,00	71,00	0,00	0,00	0,00	0,00	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used	232,00	1,0	232	1,00	232,00				0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	1,0	60			0,00	1,00	60,00	0,00	0,00	0,00	0,00	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42			0,00	1,00	42,00	0,00	0,00	0,00	0,00	0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				14,098,25		1,266,25		842,50		532,25		737,25		532,25		702,50		494,25		737,25		494,25		702,50		309,25		818,50		182,25
Additional Cost Subtotal				3,299,00		2,590,00		219,00		0,00		0,00		0,00		46,00		0,00		0,00		0,00		46,00		0,00		46,00		0,00
Subtotal				17,397,25		3,856,25		1,061,50		532,25		737,25		532,25		748,50		494,25		737,25		494,25		748,50		309,25		864,50		182,25
Overhead				2,783,56		617,00		169,84		85,16		117,96		85,16		119,76		79,08		117,96		79,08		119,76		49,48		138,32		29,16
INVESTIGATOR COST PER SUBJECT with Overhead				20,180,81		4,473,25		1,231,34		617,41		855,21		617,41		868,26		573,33		855,21		573,33		868,26		358,73		1,002,82		211,41

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D1	f	C5D15	f	C6D1	f	C6D15	f	C7D1	f	C8D1	f	C9D1	f	C10D1	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Archived alternative sample (non-fresh) - if central lab unable to ID myeloma clone	39,00	1,0	39		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	11,0	209	1,00	19,00		0,00	1,00	19,00		0,00	1,00	19,00	1,00	19,00	1,00	19,00	1,00	19,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	11,0	297	1,00	27,00		0,00	1,00	27,00		0,00	1,00	27,00	1,00	27,00	1,00	27,00	1,00	27,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	1,0	71		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for disease assessment/cytogenetics/molecular profiling	Sample collection if SOC assessment not used	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	1,0	60		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				14.098,25		702,50		182,25		818,50		182,25		702,50		702,50		702,50		702,50		497,25		343,25		86,50		124,50
Additional Cost Subtotal				3.299,00		46,00		0,00		46,00		0,00		46,00		46,00		46,00		46,00		0,00		38,00		38,00		0,00
Subtotal				17.397,25		748,50		182,25		864,50		182,25		748,50		748,50		748,50		748,50		497,25		381,25		124,50		124,50
Overhead				2.783,56		119,76		29,16		138,32		29,16		119,76		119,76		119,76		119,76		79,56		61,00		19,92		19,92
INVESTIGATOR COST PER SUBJECT with Overhead				20.180,81		868,26		211,41		1.002,82		211,41		868,26		868,26		868,26		868,26		576,81		442,25		144,42		144,42

ARM B(EPD)- Other costs

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	949,00
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	28,00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
BMA for disease assessment	Sample collection	269,12
Unscheduled Visit	Includes 1Hr SC and 1 Hr DE time	78,88
Anesthesia for BMA or BMB		316,68
Triplicate 12 Lead ECG		134,56
Additional LTFU	Paid based on EDC completion	100,34
Additional LTDA	Paid based on EDC completion	144,42
Additional Cycles - D1	Paid based on EDC completion	814,90
Additional Cycles - D15	Paid based on invoice	255,49
PROs	Invoice as incurred > C10 Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC.	23,20
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed.	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally / additional testing required	114,84
CMV PCR	If additional testing required	48,72
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting	Invoice as incurred	37,00
SAE	Includes all reports and follow up	63,00
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Pharmacy Close out	Invoice at study close	335,00

ARM B (PVD)- PER SUBJECT COST

COMPOUND :	Elranatamab	AMENDMENT :	PA4	INVESTIGATOR:	Cirino Botta
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B (Pvd)	INSTITUTION:	AOU P.Giaccone
TITLE :	A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) Or Pomalidomide, Bortezomib, Dexamethasone (Pvd) Or Carfilzomib, Dexamethasone (Kd) In Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti-CD38 Directed Therapy.			CCID:	1031
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	16,00%				

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13		VISIT 14		VISIT 15	
			Total Number of times a procedure occurs based on PSC Structure		f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D11	f	C2D1	f	C2D4	f	C2D8	f	C2D11	f	C3D1	f	C3D4	f	C3D8	f	C3D11	f	C4D1	f	C4D4
Informed Consent		43,00	1,0	43	1,00	43,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75	1,00	75,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	13,0	260	1,00	20,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00		0,00		0,00	1,00	20,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155	1,00	155,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00	1,00	72,00		0,00
Full Neurologic Exam		82,00	1,0	82	1,00	82,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00
ECOG PS		20,00	1,0	20	1,00	20,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61	1,00	61,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	4,0	464		0,00	1,00	116,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTRFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis (Arm B PVD), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)	38,00	19,0	722	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00
Saliva sample for germline comparator		24,00	1,0	24		0,00	1,00	24,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing	Local test	83,00	1,0	83	1,00	83,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Bortezomib Administration	IV/SC administration	95,00	36,0	3420		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00
	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check																																	
Study Coordinator Fee		37,00	133,3	4930,25	4,25	157,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25
Admin/Data Entry Fee		31,00	41,0	1271	2,00	62,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00
BMB for protein profiling	Sample collection	314,00	1,0	314	1,00	314,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	10,0	320		0,00	1,00	32,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00	1,00	32,00		0,00
Pharmacy Fee	IV drug prep and dispense	45,00	36,0	1620		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
Body Surface Area calculation		17,00	36,0	612		0,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114,00	1,0	114	1,00	114,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead			16.324,25		1.266,25		688,50		346,25		346,25		346,25		548,50		346,25		346,25		346,25		548,50		308,25		308,25		308,25		664,50		308,25
	PSC Subtotal with Overhead			18.936,13		1.468,85		798,66		401,65		401,65		401,65		636,26		401,65		401,65		401,65		636,26		357,57		357,57		357,57		770,82		357,57

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30	
			Total Number of times a procedure occurs based on PSC Structure		f	C4D8	f	C4D11	f	C5D1	f	C5D4	f	C5D8	f	C5D11	f	C6D1	f	C6D4	f	C6D8	f	C6D11	f	C7D1	f	C7D4	f	C7D8	f	C7D11	f	C8D1
Informed Consent		43.00	1.0	43		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75.00	1.0	75		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	13.0	260		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	12.0	864		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00	1.00	72.00
Full Neurologic Exam		82.00	1.0	82		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Neurologic Exam		69.00	12.0	828		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00
ECOG PS		20.00	1.0	20		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	4.0	464		0.00		0.00		0.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for ctDNA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis (Arm B Pvd), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)	38.00	19.0	722		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00		0.00		0.00		0.00	1.00	38.00
Saliva sample for germeline comparator		24.00	1.0	24		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 Testing	Local test	83.00	1.0	83		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Bortezomib Administration	IV/SC administration	95.00	36.0	3420	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37.00	133.3	4930.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50
Admin/Data Entry Fee		31.00	41.0	1271	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00
BMB for protein profiling	Sample collectoin	314.00	1.0	314		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Pharmacy Fee	Oral Drug prep and dispense	32.00	10.0	320		0.00		0.00	1.00	32.00		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00	1.00	32.00
Pharmacy Fee	IV drug prep and dispense	45.00	36.0	1620	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Body Surface Area calculation		17.00	36.0	612	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00	1.00	17.00
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114.00	1.0	114		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR		42.00	1.0	42		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			16,324.25		308.25		308.25		548.50		308.25		308.25		308.25		664.50		308.25		308.25		308.25		548.50		308.25		308.25		308.25		548.50
	PSC Subtotal with Overhead			18,936.13		357.57		357.57		636.26		357.57		357.57		357.57		770.82		357.57		357.57		357.57		636.26		357.57		357.57		357.57		636.26

DESCRIPTION OF COST	Comments	Cost	Frequency of Procedure	Base PSC Cost	VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36		VISIT 37		VISIT 38		VISIT 39		VISIT 40		VISIT 41	
			Total Number of times a procedure occurs based on PSC Structure		f	C8D4	f	C8D8	f	C8D11	f	C9D1	f	C9D8	f	C10D1	f	C10D8	f	EOT	f	FU	f	LTFU	f	LTD4
Informed Consent		43.00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes COVID-19 vaccine history, medical history, surgical history, treatment history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	13,0	260		0,00		0,00		0,00	1,00	20,00		0,00	1,00	20,00		0,00	1,00	20,00	1,00	20,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	12,0	864		0,00		0,00		0,00	1,00	72,00		0,00	1,00	72,00		0,00	1,00	72,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00		0,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00	1,00	69,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	4,0	464		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Pregnancy test (WOCBP only), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, HBV testing, CMV testing PCR, EBV testing PCR, Adenovirus PCR, TSH and reflex testing (T3 and free T4), PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis (Arm B PVD), Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5)	38,00	19,0	722		0,00		0,00		0,00	1,00	38,00		0,00	1,00	38,00		0,00	1,00	38,00		0,00		0,00	1,00	38,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing	Local test	83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Bortezomib Administration	IV/SC administration	95,00	36,0	3420	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute emergency contact card, infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, ICE score, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37,00	133,3	4930,25	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	1,50	55,50	1,50	55,50
Admin/Data Entry Fee		31,00	41,0	1271	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	0,50	15,50	0,50	15,50
BMB for protein profiling	Sample collection	314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	10,0	320		0,00		0,00		0,00	1,00	32,00		0,00	1,00	32,00		0,00		0,00		0,00		0,00		0,00
Pharmacy Fee	IV drug prep and dispense	45,00	36,0	1620	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00		0,00		0,00		0,00		0,00
Body Surface Area calculation		17,00	36,0	612	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00	1,00	17,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBCAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
			PSC Subtotal w/out Overhead	16.324,25		308,25		308,25		308,25		548,50		308,25		548,50		308,25		466,25		312,25		71,00		109,00
			PSC Subtotal with Overhead	18.936,13		357,57		357,57		357,57		636,26		357,57		636,26		357,57		540,85		362,21		82,36		126,44

ARM B(PVD)- ADDITIONAL TREATMENT RELATED COSTS

Additional Procedures that may not apply to all Patients					f	Screening	f	C1D1	f	C1D4	f	C1D8	f	C1D11	f	C2D1	f	C2D4	f	C2D8	f	C2D11	f	C3D1	f	C3D4	f	C3D8	f	C3D11	f	C4D1	f	C4D4
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for MRD, Molecular Profiling	Sample collection if SOC assessment not used	232,00	1,0	232	1,00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	1,0	19	1,00	19,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	1,0	27	1,00	27,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781	1,00	71,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660	1,00	60,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.324,25		1.266,25		688,50		346,25		346,25		346,25		548,50		346,25		346,25		346,25		548,50		308,25		308,25		308,25		664,50		308,25
Additional Cost Subtotal				4.110,00		2.682,00		173,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00
Subtotal				20.434,25		3.948,25		861,50		346,25		346,25		346,25		679,50		346,25		346,25		346,25		679,50		308,25		308,25		308,25		795,50		308,25
Overhead				3.269,48		631,72		137,84		55,40		55,40		55,40		108,72		55,40		55,40		55,40		108,72		49,32		49,32		49,32		127,28		49,32
INVESTIGATOR COST PER SUBJECT with Overhead				23.703,73		4.579,97		999,34		401,65		401,65		401,65		788,22		401,65		401,65		401,65		788,22		357,57		357,57		357,57		922,78		357,57

Additional Procedures that may not apply to all Patients					f	C4D8	f	C4D11	f	C5D1	f	C5D4	f	C5D8	f	C5D11	f	C6D1	f	C6D4	f	C6D8	f	C6D11	f	C7D1	f	C7D4	f	C7D8	f	C7D11	f	C8D1
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for MRD, Molecular Profiling	Sample collection if SOC assessment not used	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	1,0	19		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	1,0	27		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	1,00	71,00
SARS-CoV-2 Antigen		60,00	11,0	660		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	1,00	60,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.324,25		308,25		308,25		548,50		308,25		308,25		308,25		664,50		308,25		308,25		308,25		548,50		308,25		308,25		308,25		548,50
Additional Cost Subtotal				4.110,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00		0,00		0,00		0,00		131,00
Subtotal				20.434,25		308,25		308,25		679,50		308,25		308,25		308,25		795,50		308,25		308,25		308,25		679,50		308,25		308,25		308,25		679,50
Overhead				3.269,48		49,32		49,32		108,72		49,32		49,32		49,32		127,28		49,32		49,32		49,32		108,72		49,32		49,32		49,32		108,72
INVESTIGATOR COST PER SUBJECT with Overhead				23.703,73		357,57		357,57		788,22		357,57		357,57		357,57		922,78		357,57		357,57		357,57		788,22		357,57		357,57		357,57		788,22

Additional Procedures that may not apply to all Patients					f	C8D4	f	C8D8	f	C8D11	f	C9D1	f	C9D8	f	C10D1	f	C10D8	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for MRD, Molecular Profiling	Sample collection if SOC assessment not used	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (igG, igM, igA, igD, igE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	1,0	19		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	1,0	27		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	11,0	781		0,00		0,00		0,00	1,00	71,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	11,0	660		0,00		0,00		0,00	1,00	60,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal				16.324,25		308,25		308,25		308,25		548,50		308,25		548,50		308,25		466,25		312,25		71,00		109,00
Additional Cost Subtotal				4.110,00		0,00		0,00		0,00		131,00		0,00		131,00		0,00		0,00		38,00		38,00		0,00
Subtotal				20.434,25		308,25		308,25		308,25		679,50		308,25		679,50		308,25		466,25		350,25		109,00		109,00
Overhead				3.269,48		49,32		49,32		49,32		108,72		49,32		108,72		49,32		74,60		56,04		17,44		17,44
INVESTIGATOR COST PER SUBJECT with Overhead				23.703,73		357,57		357,57		357,57		788,22		357,57		788,22		357,57		540,85		406,29		126,44		126,44

ARM B(PVD)- Other costs

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	949,00
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	28,00
Subject/Caregiver Meal Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00

CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
Triplicate 12 Lead ECG	As clinically indicated	83,52
Unscheduled Visit	Includes 1 HR of SC and 1 HR DE time	78,88
Anesthesia for BMA or BMB		316,68
BMB for protein profiling	Sample collection	269,12
BMA for MRD, Molecular Profiling	Sample collection	364,24
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting		37,00
SAE	Includes all reports and follow up	63,00
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If required locally/ additional testing required	114,84
CMV PCR	If additional testing required	48,72
Additional LTFU	Paid based on EDC completion	82,36
Additional LTDA	Paid based on EDC completion	126,44

Additional Cycles - D1	Paid based on EDC completion	636,26
Additional Cycles - D8	Paid based on EDC completion	357,57
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68

ARM B (KD) -PER SUBJECT COST

COMPOUND :	Elranatamab	AMENDMENT :	PA4	INVESTIGATOR:	Cirino Botta				
STUDY NUMBER :	C1071032	ARM/COHORT :	Arm B (Kd)	INSTITUTION:	AOU Giaccone				
TITLE :	A PHASE 3, OPEN-LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMAB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB, DEXAMETHASONE (PVd) OR CARFILZOMIB, DEXAMETHASONE (Kd) IN PARTICIPANTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA WHO RECEIVED PRIOR ANTI-CD38 DIRECTED THERAPY.			CCID:	1031				
COUNTRY/Currency :	Italy - EUR								
OVERHEAD	16,00%								

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Screening	f	C1D1	f	C1D2	f	C1D8	f	C1D9	f	C1D15	f	C1D16	f	C1D22	f	C2D1	f	C2D2	f	C2D8	f	C2D9
Informed Consent		43.00	1.0	43	1.00	43.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75.00	1.0	75	1.00	75.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20.00	5.0	100	1.00	20.00	1.00	20.00		0.00		0.00		0.00	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00
Full Physical Exam	Includes height/weight and vital signs where applicable	155.00	1.0	155	1.00	155.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72.00	9.0	648		0.00	1.00	72.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	72.00		0.00		0.00		0.00
Full Neurologic Exam		82.00	1.0	82	1.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Targeted Neurologic Exam		69.00	12.0	828		0.00	1.00	69.00		0.00		0.00		0.00	1.00	69.00		0.00		0.00	1.00	69.00		0.00		0.00		0.00
ECOG PS		20.00	1.0	20	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Single 12 Lead ECG	Includes interpretation and report	61.00	1.0	61	1.00	61.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Triplicate 12 Lead ECG	Includes interpretation and report	116.00	6.0	696		0.00	1.00	116.00		0.00		0.00		0.00	1.00	116.00		0.00		0.00		0.00		0.00		0.00		0.00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE),Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38.00	16.0	608	1.00	38.00	1.00	38.00	1.00	38.00	1.00	38.00		0.00	1.00	38.00		0.00	1.00	38.00	1.00	38.00		0.00		0.00		0.00
Saliva sample for germline comparator		24.00	1.0	24		0.00	1.00	24.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
SARS-CoV-2 Testing		83.00	1.0	83	1.00	83.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37.00	155.3	5744.25	4.25	157.25	3.50	129.50	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.25	120.25	3.50	129.50	3.25	120.25	3.25	120.25		0.00
Admin/Data Entry Fee		31.00	49.0	1519	2.00	62.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00	1.00	31.00
Carfilzomib Administration	IV administration	95.00	41.0	3895		0.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00	1.00	95.00		0.00	1.00	95.00		0.00	1.00	95.00	1.00	95.00
Pharmacy Fee	IV drug prep and dispense	45.00	41.0	1845		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00
Pharmacy Fee	Oral Drug prep and dispense	32.00	7.0	224		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	32.00		0.00		0.00		0.00
BMB for protein profiling		314.00	1.0	314	1.00	314.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114.00	1.0	114	1.00	114.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
CMV PCR		42.00	1.0	42	1.00	42.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			17,120.25		1,266.25		671.50		329.25		329.25		291.25		534.25		291.25		189.25		511.50		151.25		291.25		171.00
	PSC Subtotal with Overhead			19,859.49		1,468.85		778.94		381.93		381.93		337.85		619.73		337.85		219.53		593.34		175.45		337.85		198.36

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 13		VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24	
			Total Number of times a procedure occurs based on PSC Structure		f	C2D15	f	C2D16	f	C2D22	f	C3D1	f	C3D2	f	C3D8	f	C3D9	f	C3D15	f	C3D16	f	C4D1	f	C4D2	f	C4D8
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	5,0	100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	9,0	648		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828	1,00	69,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00	1,00	69,00		0,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696	1,00	116,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38,00	16,0	608	1,00	38,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00	1,00	38,00		0,00	1,00	38,00		0,00		0,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing		83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37,00	155,3	5744,25	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25
Admin/Data Entry Fee		31,00	49,0	1519	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00
Carfilzomib Administration	IV administration	95,00	41,0	3895	1,00	95,00	1,00	95,00		0,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00
Pharmacy Fee	IV drug prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00		0,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	7,0	224		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00
BMB for protein profiling		314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBeAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
			PSC Subtotal w/out Overhead																									
				17.120,25		514,25		291,25		151,25		511,50		291,25		291,25		291,25		398,25		291,25		627,50		291,25		291,25
			PSC Subtotal with Overhead			19.859,49		596,53		337,85		175,45		593,34		337,85		337,85		337,85		461,97		337,85		727,90		337,85

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35		VISIT 36	
			Total Number of times a procedure occurs based on PSC Structure		f	C4D9	f	C4D15	f	C4D16	f	C5D1	f	C5D2	f	C5D8	f	C5D9	f	C5D15	f	C5D16	f	C6D1	f	C6D2	f	C6D8
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	5,0	100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	9,0	648		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00		0,00		0,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00		0,00		0,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cfDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38,00	16,0	608		0,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00
		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
		83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check																											
Admin/Data Entry Fee		31,00	49,0	1519	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00
Carfilzomib Administration	IV administration	95,00	41,0	3895	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00
Pharmacy Fee	IV drug prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	7,0	224		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00		0,00		0,00	1,00	32,00		0,00		0,00
BMB for protein profiling		314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00

DESCRIPTION OF COST	Comments	Frequency of Procedure		Total PSC	VISIT 37		VISIT 38		VISIT 39		VISIT 40		VISIT 41		VISIT 42		VISIT 43		VISIT 44		VISIT 45		VISIT 46		VISIT 47		VISIT 48		VISIT 49	
		COST	Total Number of times a procedure occurs based on PSC Structure		f	C6D9	f	C6D15	f	C6D16	f	C7D1	f	C7D2	f	C7D8	f	C7D9	f	C7D15	f	C7D16	f	EOT	f	FU	f	LTFU	f	LTDA
Informed Consent		43,00	1,0	43		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Demographics/Treatment History	Includes medical history, surgical history, treatment history and COVID-19 vaccine history	75,00	1,0	75		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
PROs	Includes EORTC QLQ-C30, MY20, EQ-5D-5L, WPAI and PGIC	20,00	5,0	100		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	20,00	1,00	20,00		0,00		0,00
Full Physical Exam	Includes height/weight and vital signs where applicable	155,00	1,0	155		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Physical Exam	Includes height/weight and vital signs where applicable	72,00	9,0	648		0,00		0,00		0,00	1,00	72,00		0,00		0,00		0,00		0,00		0,00	1,00	72,00	1,00	72,00		0,00		0,00
Full Neurologic Exam		82,00	1,0	82		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Targeted Neurologic Exam		69,00	12,0	828		0,00		0,00		0,00	1,00	69,00		0,00		0,00		0,00		0,00		0,00	1,00	69,00	1,00	69,00		0,00		0,00
ECOG PS		20,00	1,0	20		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Single 12 Lead ECG	Includes interpretation and report	61,00	1,0	61		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Triplicate 12 Lead ECG	Includes interpretation and report	116,00	6,0	696		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	116,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits, if required - SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE), Serum Beta-2 microglobulin, Hematology, Chemistry, SARS-CoV-2 testing, PT/INR, Blood sample for sBCMA levels, Blood sample for cDNA analysis, Serum sample for circulating proteins and/or metabolite analysis, Blood sample for TCR sequencing, Blood sample for immune cell profiling, Retained Research Sample for genetics (Prep D1.5), TSH and reflex testing (T3 and T4)	38,00	16,0	608		0,00		0,00		0,00	1,00	38,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00		0,00		0,00	1,00	38,00
Saliva sample for germline comparator		24,00	1,0	24		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Testing		83,00	1,0	83		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Study Coordinator Fee	Includes: Distribute Emergency contact card and infection reminder card, Eligibility criteria, IRT registration, Randomization, Disease characteristics, Healthcare resource use, ICE score, Serious and nonserious AE monitoring, Concomitant therapy, Subsequent anticancer therapies/date of progression, Survival status, Disease response assessment per IMWG criteria, Contraception check	37,00	155,3	5744,25	3,25	120,25	3,25	120,25	3,25	120,25	3,50	129,50	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	3,25	120,25	1,50	55,50	1,50	55,50
Admin/Data Entry Fee		31,00	49,0	1519	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	1,00	31,00	0,50	15,50	0,50	15,50
Carfilzomib Administration	IV administration	95,00	41,0	3895	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	1,00	95,00	0,00	0,00	0,00	0,00
Pharmacy Fee	IV drug prep and dispense	45,00	41,0	1845	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	1,00	45,00	0,00	0,00	0,00	0,00
Pharmacy Fee	Oral Drug prep and dispense	32,00	7,0	224		0,00		0,00		0,00	1,00	32,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for protein profiling		314,00	1,0	314		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
HBV testing	Fee includes HBsAg, HBcAb and HBsAb	114,00	1,0	114		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR		42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
	PSC Subtotal w/out Overhead																													
				17.120,25		291,25		291,25		291,25		511,50		291,25		291,25		291,25		291,25		291,25		466,25		312,25		71,00		109,00
	PSC Subtotal with Overhead																													
				19.859,49		337,85		337,85		337,85		593,34		337,85		337,85		337,85		337,85		337,85		540,85		362,21		82,36		126,44

ARM B (KD)- ADDITIONAL TREATMENT RELATED COSTS

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Screening	f	C1D1	f	C1D2	f	C1D8	f	C1D9	f	C1D15	f	C1D16	f	C1D22	f	C2D1	f	C2D2	f	C2D8	f	C2D9	
ECHO	Either Echo or MUGA	740,00	1,0	740	1,00	740,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
MUGA	Either Echo or MUGA	618,00	1,0	618	1,00	618,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162	1,00	162,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753	1,00	753,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMB for Protein profiling	Optional collection	232,00	1,0	232	1,00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Urine Pregnancy Test	WOCBP only	19,00	8,0	152	1,00	19,00	1,00	19,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00	
Serum Pregnancy Test	WOCBP only	27,00	8,0	216	1,00	27,00	1,00	27,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00	
SARS-CoV-2 PCR		71,00	8,0	568	1,00	71,00	1,00	71,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00	
SARS-CoV-2 Antigen		60,00	8,0	480	1,00	60,00	1,00	60,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00	
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00	1,00	42,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling		232,00	1,0	232	1,00	232,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Per Subject Cost Subtotal					17.120,25		1.266,25		671,50		329,25		329,25		291,25		534,25		291,25		189,25		511,50		151,25		291,25		171,00
Additional Cost Subtotal					4.271,00		2.914,00		219,00		0,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00
Subtotal					21.391,25		4.180,25		890,50		329,25		329,25		291,25		534,25		291,25		189,25		688,50		151,25		291,25		171,00
Overhead					3.422,60		668,84		142,48		52,68		52,68		46,60		85,48		46,60		30,28		110,16		24,20		46,60		27,36
INVESTIGATOR COST PER SUBJECT with Overhead					24.813,85		4.849,09		1.032,98		381,93		381,93		337,85		619,73		337,85		219,53		798,66		175,45		337,85		198,36

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D15	f	C2D16	f	C2D22	f	C3D1	f	C3D2	f	C3D8	f	C3D9	f	C3D15	f	C3D16	f	C4D1	f	C4D2	f	C4D8	
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Urine Pregnancy Test	WOCBP only	19,00	8,0	152		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00	
Serum Pregnancy Test	WOCBP only	27,00	8,0	216		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00	
SARS-CoV-2 PCR		71,00	8,0	568		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00	
SARS-CoV-2 Antigen		60,00	8,0	480		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00	
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling		232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Per Subject Cost Subtotal					17.120,25	514,25		291,25		151,25		511,50		291,25		291,25		291,25		398,25		291,25		627,50		291,25		291,25	
Additional Cost Subtotal					4.271,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00		0,00
Subtotal					21.391,25	514,25		291,25		151,25		688,50		291,25		291,25		291,25		398,25		291,25		804,50		291,25		291,25	
Overhead					3.422,60	82,28		46,60		24,20		110,16		46,60		46,60		46,60		63,72		46,60		128,72		46,60		46,60	
INVESTIGATOR COST PER SUBJECT with Overhead					24.813,85	596,53		337,85		175,45		798,66		337,85		337,85		337,85		461,97		337,85		933,22		337,85		337,85	

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C4D9	f	C4D15	f	C4D16	f	C5D1	f	C5D2	f	C5D8	f	C5D9	f	C5D15	f	C5D16	f	C6D1	f	C6D2	
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Urine Pregnancy Test	WOCBP only	19,00	8,0	152		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00	1,00	19,00		0,00	
Serum Pregnancy Test	WOCBP only	27,00	8,0	216		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00	1,00	27,00		0,00	
SARS-CoV-2 PCR		71,00	8,0	568		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00	1,00	71,00		0,00	
SARS-CoV-2 Antigen		60,00	8,0	480		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00	1,00	60,00		0,00	
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling		232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	
Per Subject Cost Subtotal					17.120,25		291,25		291,25		291,25		511,50		291,25		291,25		291,25		291,25		291,25		627,50		291,25
Additional Cost Subtotal					4.271,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00		177,00		0,00
Subtotal					21.391,25		291,25		291,25		291,25		688,50		291,25		291,25		291,25		291,25		291,25		804,50		291,25
Overhead					3.422,60		46,60		46,60		46,60		110,16		46,60		46,60		46,60		46,60		46,60		128,72		46,60
INVESTIGATOR COST PER SUBJECT with Overhead					24.813,85		337,85		337,85		337,85		798,66		337,85		337,85		337,85		337,85		337,85		933,22		337,85

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C6D8	f	C6D9	f	C6D15	f	C6D16	f	C7D1	f	C7D2	f	C7D8	f	C7D9	f	C7D15	f	C7D16	f	EOT	f	FU	f	LTFU	f	LTDA
ECHO	Either Echo or MUGA	740,00	1,0	740		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
MUGA	Either Echo or MUGA	618,00	1,0	618		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest X-Ray	To assess respiratory infection. Either X-Ray or CT not both	162,00	1,0	162		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Chest CT	To assess respiratory infection. Either X-Ray or CT not both	753,00	1,0	753		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMB for Protein profiling	Optional collection	232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Central Lab - includes collection, processing and shipping	For FU and LTFU visits if required: SPEP, SIFE, FLC, UPEP, UIFE, Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	38,00	2,0	76		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00	1,00	38,00	1,00	38,00		0,00
Urine Pregnancy Test	WOCBP only	19,00	8,0	152		0,00		0,00		0,00		0,00	1,00	19,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Serum Pregnancy Test	WOCBP only	27,00	8,0	216		0,00		0,00		0,00		0,00	1,00	27,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 PCR		71,00	8,0	568		0,00		0,00		0,00		0,00	1,00	71,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
SARS-CoV-2 Antigen		60,00	8,0	480		0,00		0,00		0,00		0,00	1,00	60,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
CMV PCR	If screening test performed >7 days	42,00	1,0	42		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
BMA for MRD, disease assessment, cytogenetics and Molecular Profiling		232,00	1,0	232		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00		0,00
Per Subject Cost Subtotal						291,25		291,25		291,25		291,25		511,50		291,25		291,25		291,25		291,25		291,25		466,25		312,25		71,00		109,00
Additional Cost Subtotal						0,00		0,00		0,00		0,00		177,00		0,00		0,00		0,00		0,00		0,00		0,00		38,00		38,00		0,00
Subtotal						291,25		291,25		291,25		291,25		688,50		291,25		291,25		291,25		291,25		291,25		466,25		350,25		109,00		109,00
Overhead						46,60		46,60		46,60		46,60		110,16		46,60		46,60		46,60		46,60		46,60		74,60		56,04		17,44		17,44
INVESTIGATOR COST PER SUBJECT with Overhead						337,85		337,85		337,85		337,85		798,66		337,85		337,85		337,85		337,85		337,85		540,85		406,29		126,44		126,44

ARM B (KD)- Other study level costs:

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	Comments	Cost
Please see 'Arm A' budget for Site fees		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	949,00
Subject/Caregiver Travel Reimbursement	Per on site visit. Reimbursed up to amount shown, must provide receipts where applicable. Per visit for 20% of subjects.	28,00
Subject/Caregiver Meal Reimbursement	Per meal/onsite visit only, reimbursed up to amount shown, must provide receipts where applicable.	24,00
CT Chest	CT or MRI, but not both. Includes Interpretation and report	873,48
CT Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.052,12
CT Pelvis	CT or MRI, but not both. Includes Interpretation and report	870,00
CT Brain	CT or MRI, but not both. Includes Interpretation and report	992,96
MRI Chest	CT or MRI, but not both. Includes Interpretation and report	1.375,76
MRI Abdomen	CT or MRI, but not both. Includes Interpretation and report	1.126,36
MRI Pelvis	CT or MRI, but not both. Includes Interpretation and report	1.200,60
MRI Brain	CT or MRI, but not both. Includes Interpretation and report	1.418,68
PET/CT whole body	CT or MRI, but not both. Includes Interpretation and report	3.165,64
PET/CT Skull base to mid thigh	CT or MRI, but not both. Includes Interpretation and report	2.535,76
PET/CT Partial Body	CT or MRI, but not both. Includes Interpretation and report	2.460,36
BMA for disease assessment	Sample Collection Additional timepoints	132,24
Unscheduled Visit	Includes 1hr SC and 1hr DE time. Invoice for other activities completed	78,88
Anesthesia for BMA or BMB		316,68
Dry Ice	Per shipment	18,00
Triplicate 12 Lead ECG	As clinically indicated	134,56
Whole Body MRI	CT or MRI, but not both. Includes Interpretation and report	1.385,04
Chest X-ray	Includes Interpretation and report	187,92
Chemistry	Local Lab	55,68
Hematology	Local Lab	30,16
PT/INR	Local Lab	18,56
Hepatitis Panel	Local Lab	75,40
SARS-CoV2	If additional testing required	69,60
Reconsenting		37,00

SAE	Includes all reports and follow up	63,00
ECHO	Either Echo or MUGA if additional tests needed	858,40
MUGA	Either Echo or MUGA if additional tests needed	716,88
Cardiologist Consultation	Per Hour - Invoice as incurred if needed	124,00
Neurologist Consultation	Per Hour - Invoice as incurred if needed	128,00
Dermatologist Consultation	Per Hour - Invoice as incurred if needed	81,00
FISH	If local/ additional testing required	114,84
CMV PCR	If additional testing required	48,72
Additional LTFU	Paid based on EDC completion	82,36
Additional LTDA	Paid based on EDC completion	126,44
Additional cycles - D1	Additional cycles past C7 - Paid based on EDC entry	593,34
Additional cycles - D2	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D8	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D9	Additional cycles past C7 - Paid based on EDC entry	337,85
Additional cycles - D15	Additional cycles past C7 - Paid based on EDC entry	337,85
HBV testing; HBsAg, HBcAb and HBsAb - unscheduled (local lab)	Invoice as incurred	132,24
HBV DNA viral load (local lab analysis)	Invoice as incurred	103,24
HCV antibody testing (local lab analysis)	Invoice as incurred	56,84
HIV-1 and HIV-2 antibody, single assay (local lab analysis)	Invoice as incurred	55,68
Additional cycles - D16	Additional cycles past C7 - Paid based on EDC entry	337,85



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