

AMENDMENT N° 2
(hereinafter “**Amendment**”)

is effective as of the date of last signature (hereinafter
“**Effective date**”)

to the
**AGREEMENT FOR THE CONDUCT OF A
CLINICAL TRIAL ON MEDICINAL
PRODUCTS** dated 29 April 2025,

This Amendment is made by and between

- (1) Azienda Ospedaliera Universitaria Policlinico
“P. Giaccone” di Palermo (hereinafter referred
to as the “**Institution**”), with registered office
at Via del Vespro 129, Palermo - Italy Tax
Code and VAT No. 05841790826, represented
by its Legal Representative, Dr Maria Grazia
Furnari, in the capacity as General Director,
who is granted the appropriate powers to sign
this document

and

(2) Parexel International (IRL) Limited, with
registered office at 70 Sir John Rogerson's
Quay, Dublin 2, Ireland, VAT no. IE-
3249971HH, represented by its authorized
Representative Nicola Sotira. (hereinafter
referred to as “**CRO**”), acting on behalf of
Boehringer Ingelheim International GmbH
(hereinafter referred to as the “**Sponsor**”),
pursuant to an appropriate
delegation/mandate/power of attorney
conferred on 20 December 2024

hereinafter individually/collectively the
“**Party/Parties**”.

regarding

Protocol No: 1404-0044 (hereinafter “**Protocol**”)
“A randomised, double-blind, placebo-controlled,
multicentre, Phase III trial evaluating long-term
efficacy and safety of survodutide weekly injections in
adult participants with noncirrhotic non-alcoholic

EMENDAMENTO NUMERO 2
(qui di seguito “**Emendamento**”)
decorrerà a partire dalla data dell’ultima firma

(di seguito “**Data di decorrenza**”)

al
**CONTRATTO PER LA CONDUZIONE DELLA
SPERIMENTAZIONE CLINICA SU
MEDICINALI** datato 29 aprile 2025,

Il presente Emendamento è stipulato da e tra

- (1) Azienda Ospedaliera Universitaria
Policlinico “P. Giaccone” di Palermo (di
seguito “**Ente**”), con sede legale in Via del
Vespro 129, Palermo - Italia C.F. e P.IVA n.
05841790826, in persona del Legale
Rappresentante, Dott.ssa Maria Grazia Furnari,,
in qualità di Direttrice Generale munita di
idonei poteri di firma

E

(2) Parexel International (IRL) Limited, con
sede legale in 70 Sir John Rogerson's Quay,
Dublino 2, Irlanda, C.F. e P.IVA n. IE-
3249971HH, in persona del suo
Rappresentante autorizzato, Nicola Sotira (di
seguito “**CRO**”), che agisce per conto di
Boehringer Ingelheim International GmbH (di
seguito “**Promotore**”), in forza di idonea
delega/mandato/procura conferita in data 20
dicembre 2024

Indicati singolarmente/ collettivamente con
“**Parte/Parti**”.

In relazione a

Protocollo: 1404-0044 (di seguito “**Protocollo**”)
“*Studio di fase III, randomizzato, in doppio cieco,
controllato verso placebo, multicentrico, volto a
valutare l’efficacia e la sicurezza a lungo termine di
iniezioni settimanali di survodutide a partecipanti*

steatohepatitis/metabolic dysfunction-associated steatohepatitis (NASH/MASH) and (F2) - (F3) stage of liver fibrosis”
(hereinafter “**Study**”)
Survodutide (BI 456906) (hereinafter “**Study Drug**“)

WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug;

WHEREAS, SPONSOR has contracted with Parexel International (IRL) or an Affiliate (hereinafter “**CRO**”) (under a separate written agreement) to act as SPONSOR’s contractor and designee in managing the Study for SPONSOR, in accordance with the Protocol; and

WHEREAS, the Parties have entered into the above-referred Clinical Site Agreement dated 29 April 2025 (hereinafter “**Agreement**”);

WHEREAS, due to Protocol amendment # 5.0 dated 25 July 2025 (hereinafter “**Protocol amendment**”) the Parties agree to amend the agreement to include revised budget in accordance with the changes in the said Protocol amendment.

WHEREAS, the Parties are jointly willing to amend the above-referred Agreement;

Now, therefore the above-referred Agreement shall be amended and the following amended wordings shall be effective as of IRB/EC/RA approval of the above mentioned Protocol Amendment (30 January 2026).

1. Due to Protocol amendment the Annex A – Payments terms and Budget is being deleted in its entirety and replaced with the revised

adulti con steatoepatite non alcolica non cirrotica/steatoepatite associata a disfunzione metabolica (NASH/MASH) e fibrosi epatica in stadio (F2) - (F3)”
(di seguito “**Studio**”)
Survodutide (BI 456906) (di seguito “**Medicinale Sperimentale**”)

PREMESSO che, il Promotore è lo sponsor dello Studio multicentrico per la valutazione clinica del Medicinale Sperimentale;

PREMESSO CHE, il Promotore ha stipulato un contratto con Parexel International (IRL) o un affiliato (di seguito “**CRO**”) (in base a un separato accordo scritto) per agire in qualità di contraente e delegato del Promotore nella gestione dello Studio per conto del Promotore, in conformità con il Protocollo; e

PREMESSO CHE le Parti hanno stipulato il suddetto **CONTRATTO PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA SU MEDICINALI** in data 29 aprile 2025 (di seguito “**Contratto**”);

PREMESSO CHE, a seguito dell'emendamento al Protocollo n. 5.0 del 25 luglio 2025 (di seguito “**Emendamento al Protocollo**”), le Parti convengono di modificare il Contratto per includere il budget rivisto in conformità alle modifiche apportate al suddetto Emendamento al Protocollo.

PREMESSO CHE, le Parti sono congiuntamente disposte a modificare il Contratto di cui sopra;

Pertanto, il Contratto sopra menzionato sarà modificato e le seguenti formulazioni modificate saranno efficaci a partire dalla data dell’approvazione dell’Emendamento al Protocollo da parte del CE / IRB / AR (30 gennaio 2026).

1. A seguito dell’Emendamento al Protocollo, l’ALLEGATO A – Termini di pagamento e Budget viene eliminato nella sua interezza e sostituito con

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| <p>Annex A - Payments terms and Budget attached herein.</p> <p>In the event of a conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall take precedence.</p> <p>All other terms and conditions of the above-referred Agreement remain unchanged and in full force and effect.</p> <p>IN WITNESS WHEREOF, the Parties have executed this Amendment. In the event that the Parties execute this Amendment by exchange of electronically signed copies or facsimile signed copies, upon being signed by all Parties, the Parties agree that this Amendment will become effective and legally binding and that facsimile copies and/or electronic signatures will constitute proof of a binding agreement with the expectation that original copies may later be exchanged in good faith.</p> | <p>l'ALLEGATO A - Termini di pagamento e Budget rivisto qui allegato.</p> <p>In caso di conflitto tra i termini del presente Emendamento e quelli del Contratto, prevarranno i termini del presente Emendamento.</p> <p>Tutti gli altri termini e condizioni del Contratto sopra menzionato rimangono invariati e pienamente validi ed efficaci.</p> <p>IN FEDE DI QUANTO SOPRA ESPOSTO, Le Parti hanno sottoscritto il presente Emendamento. Nel caso in cui le Parti sottoscrivano il presente Emendamento mediante scambio di copie firmate elettronicamente o di copie firmate via facsimile, una volta sottoscritte da tutte le Parti, le Parti convengono che il presente Emendamento diventerà efficace e giuridicamente vincolante e che le copie facsimile e/o le firme elettroniche costituiranno prova di un accordo vincolante, con l'aspettativa che le copie originali possano essere successivamente scambiate in buona fede.</p> |
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(1) **On behalf of the Sponsor Boehringer Ingelheim
International GmbH
Parexel International (IRL) Limited on behalf of
Boehringer Ingelheim International GmbH: / Per
il Promotore: Parexel International (IRL)
Limited per conto di Boehringer Ingelheim
International GmbH**

(Signature of Authorized Official) / Firma
Dott / Dr Nicola Sotira

(Typed or Printed Name) / Nome

Date / Data

(2) **Institution Name / Nome dell'Ente: Azienda
Ospedaliera Universitaria Policlinico "P.
Giaccone" di Palermo
General Director / Direttrice Generale**

(Signature of Authorized Official) / Firma

Dr / Dott.ssa Maria Grazia Furnari

(Typed or Printed Name) / Nome

Date / Data

**For acknowledgement of the provisions that
concern him: the Principal Investigator / Per
presa visione delle disposizioni che lo
riguardano: lo Sperimentatore Principale:**

(Signature of Investigator) / Firma

Prof Salvatore Petta

(Typed or Printed Name) / Nome

Date / Data

1. Payee Details / Dettagli del Beneficiario

| Payee / Beneficiario | Payee Details / Dettagli del Beneficiario |
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| Protocol Number / Numero di Protocollo | 1404-0044 |
| Site Number / Numero del Centro | ITA3 |
| Payee Name (hereinafter “Payee”) / Nome del Beneficiario (di seguito “Beneficiario”) | Azienda Ospedaliera Universitaria Policlinico “P. Giaccone” |
| Payee Address / Indirizzo del Beneficiario | Via del Vespro 129 |
| Address Line 2 / Riga Indirizzo 2 | NA |
| Address Line 3 / Riga Indirizzo 3 | NA |
| Province/State/Country / Provincia/Stato/Paese | Palermo |
| City / Città | Palermo |
| Postal Code / Codice Postale | 90127 |
| Country / Paese | Italy / Italia |
| Payee Contact / Recapiti del Beneficiario | Dott.ssa Rosaria Mosca |
| Payee Contact Phone Number / Numero di telefono del Beneficiario | 0039 0916555535 |
| Remittance E-mail Address / Indirizzo e-mail per le ricevute | Rosaria.mosca@policlinico.pa.it |
| General Finance contact e-mail address / Indirizzo e-mail del referente della Direzione Generale Finanza | Convenzioni.sperimentazioni@policlinico.pa.it |
| NPI | NA |
| Applicable Tax ID/VAT or GST Registration/TIN/SSN / Numero di identificazione del contribuente [TIN]/Numero di previdenza sociale [SSN]) | 05841790826 |
| Bank Account Holder Name / Nome dell’intestatario del conto corrente bancario | Azienda Ospedaliera Universitaria Policlinico “P. Giaccone” |
| Bank Account Number / Numero conto Corrente bancario | 218030 |
| IBAN (18-digit International Bank Account Number) | IT86P0100504600000000218030 |
| Bank Name / Nome dell’istituto di credito | Banca Nazionale del Lavoro S.p.A. Via Roma n. 297 |
| Bank Routing Number / Numero di routing della banca | NA |
| Bank Branch Number / Codice filiale dell’istituto di credito | NA |
| Bank Identification Code/SWIFT Code / Codice di identificazione bancaria / Codice SWIFT | BNLIITRR |
| Payment Terms / Termini di pagamento | 45 (forty-five) days / 45 (quarantacinque) giorni |
| Payment Frequency / Frequenza di pagamento | Quarterly - Trimestrale |
| Payment Currency / Valuta | EUR |

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| <p>To ensure proper payment please ensure that all fields above are completed.</p> <p>In the event that Payee details are modified during the course of the study, the parties agree that no amendments to this Agreement shall be required, provided that Payee provides written notification to CRO with revised payee details to the following e-mail address, InvestigatorPaymentHelpDesk@parexel.com. CRO's Investigator Payment Office will attempt to independently verify banking information changes to ensure they are valid. If Payee does not respond to these verification attempts, CRO's Investigator Payment Office will modify the banking information as per the email but accepts no liability for incorrect payee details provided by the Payee, its representative or any other third party. Any payments that are fraudulently misdirected will not be re-paid.</p> | <p>Al fine di consentire il corretto pagamento, assicurarsi di aver compilato tutti i campi sopra riportati.</p> <p>In caso di variazione dei dati del Beneficiario nel corso dello Studio, le parti convengono di non emendare il presente Contratto, a condizione che l'Ente comunichi per iscritto alla CRO i dati aggiornati del beneficiario al seguente indirizzo e-mail InvestigatorPaymentHelpDesk@PAREXEL.com. L'Investigator Payment Office della CRO tenterà di verificare in modo indipendente le modifiche alle informazioni bancarie per garantire che siano valide. Se il Beneficiario non risponde a questi tentativi di verifica, l'Investigator Payment Office della CRO modificherà le informazioni bancarie come indicato nell'e-mail ma non si assume alcuna responsabilità per i dati errati del beneficiario forniti dal Beneficiario, dal suo rappresentante o da qualsiasi altra terza parte. Eventuali pagamenti fraudolentemente indirizzati in modo errato non verranno rimborsati.</p> |
| <p><u>2. Enrolment</u></p> | <p><u>2. Arruolamento</u></p> |
| <p>This study is designed to evaluate Subjects in accordance with the Protocol. The Investigator on behalf of the Institution will use best efforts to enrol Subjects. When enrolment is complete for the study, the Institution will be notified in writing and will discontinue enrolling Subjects.</p> | <p>Il presente Studio è finalizzato a valutare i pazienti in conformità al Protocollo. Lo Sperimentatore, per conto dell'Ente, farà quanto in suo potere per arruolare pazienti. Una volta completato l'arruolamento per lo Studio, l'Ente sarà informato per iscritto e provvederà a interrompere l'arruolamento dei pazienti.</p> |
| <p><u>3. Per Subject Fees:</u></p> | <p><u>3. Costi per paziente:</u></p> |
| <p>The amount to be paid to the Payee per completed subject is outlined in the attached Detailed Budget. Invoices should be submitted by Payee to CRO on a quarterly basis and all payments will be made electronically within forty-five (45) days of receipt, review and approval of an invoice and will be based on completed visits entered in the subject EDC (electronic data capture system) according to agreed-upon criteria.</p> | <p>L'importo da corrispondere al Beneficiario per ogni soggetto valutabile completato è specificato nel Budget dettagliato allegato. Il Beneficiario dovrà presentare le fatture alla CRO su base trimestrale e tutti i pagamenti saranno effettuati elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione di una fattura e si baseranno sulle visite completate inserite nell'EDC del soggetto (sistema elettronico di acquisizione dati) secondo criteri concordati.</p> |

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| <p>4. Conditional Fees and Invoiceable Fees:</p> | <p>4. Costi condizionali e fatturabili:</p> |
| <p>Payment for other conditional fees or expenses that are not included in the Per Subject Fees (as defined in Section 9) will be made according to the below rates as outlined in the below attached Detailed Budget:</p> | <p>Il pagamento di altri costi o spese condizionali non inclusi nei Costi per paziente (come definito nella Sezione 3) sarà effettuato secondo le tariffe sotto indicate, come specificato nel Budget dettagliato allegato:</p> |
| <p>PRE-SCREENING PAYMENT: Payee will receive a payment up to the maximum amount of € 994.93 per subject who completes all pre-screening activities upon CRO's receipt of an undisputed, detailed, itemized invoice, provided that the number of pre-screened subjects paid hereunder will be capped at a ratio of 8:1 (meaning the Payee will be paid a maximum of eight (8) pre-screened subjects per one (1) enrolled Subject). Payments for pre-screened subjects over (8:1 ratio) may require review and further approval by SPONSOR or CRO in writing. Pre-screening payment is not applicable for subjects who proceed directly to Screening without this preliminary pre-screening process.</p> | <p>PAGAMENTO PRE-SCREENING: Il beneficiario riceverà un pagamento fino all'importo massimo di € 994.93 per soggetto che completa tutte le attività di pre-screening al ricevimento da parte della CRO di una fattura dettagliata, non contestata e dettagliata, a condizione che il numero di soggetti pre-screening pagati ai sensi del presente documento sia limitato a un rapporto di 8:1 (il che significa che al beneficiario verrà pagato un massimo di otto (8) soggetti pre-screening per un (1) soggetto iscritto). I pagamenti per soggetti pre-screening superiori a (rapporto 8:1) potrebbero richiedere la revisione e un'ulteriore approvazione scritta da parte dello Sponsor o della CRO. Il pagamento pre-screening non è applicabile ai soggetti che procedono direttamente allo Screening senza questa procedura preliminare di pre-screening.</p> |
| <p>SCREENING FAILURE: Screening Failures will be reimbursed according to actual procedures performed, based on the individual item costs outlined on the below-attached Detailed Budget, upon entry of complete information into EDC and CRO's receipt of an undisputed, detailed, itemized invoice. All Screen Failures, will be reimbursed for 100% of actual incurred procedures and invoiceable costs as outlined on the below-attached Detailed Budget. Institution will make every effort to avoid unnecessary procedures and to establish if a Subject is a screen failure based on the eligibility criteria defined by the Protocol. When the site reaches or exceeds a screen failure ratio of 4:1 (four screen failure Subject that have performed either 4 MRI-PDFF or 4 liver biopsy, whichever occurs first, per one enrolled Subject), the CRO, Sponsor or delegate may review the patient characteristics and discuss the targeting of appropriate patients with the site. The SPONSOR, Sponsor delegate or CRO has the right to limit, reduce or halt future screening based on this evaluation. The site is allowed to continue screening activities during the evaluation process until otherwise notified by the SPONSOR or CRO. A screening failure is considered a Subject who signs the informed consent form and completes screening but fails under inclusion/exclusion criteria and will not be enrolled.</p> | <p>SCREENING FAILURE: I fallimenti dello screening saranno rimborsati in base alle procedure effettivamente eseguite, in base ai costi delle singole voci indicati nel Budget dettagliato allegato di seguito, previa immissione di informazioni complete nell'EDC e ricezione da parte della CRO di una fattura dettagliata, incontestata e dettagliata. Tutti i fallimenti dello screening saranno rimborsati al 100% delle procedure effettivamente sostenute e dei costi fatturabili, come indicato nel Budget dettagliato allegato di seguito. L'Ente farà ogni sforzo per evitare procedure non necessarie e per stabilire se un soggetto è un fallimenti dello screening in base ai criteri di idoneità definiti dal Protocollo. Quando l'Ente raggiunge o supera un rapporto di fallimenti dello screening di 4:1 (quattro soggetti con fallimenti dello screening che hanno eseguito 4 MRI-PDFF o 4 biopsie epatiche, a seconda di quale evento si verifichi per primo, per un soggetto arruolato), la CRO, il Promotore o un delegato possono esaminare le caratteristiche del paziente e discutere con il centro l'individuazione dei pazienti appropriati. Il Promotore, il delegato del Promotore o la CRO hanno il diritto di limitare, ridurre o interrompere i futuri screening in base a questa valutazione. L'Ente è autorizzato a continuare le attività di screening durante il processo</p> |

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| | <p>di valutazione fino a diversa comunicazione da parte del Promotore o della CRO. Si considera fallimento dello screening quando il Soggetto firma il modulo di consenso informato e completa lo screening, ma non soddisfa i criteri di inclusione/esclusione e non verrà arruolato.</p> |
| <p>RE-SCREENING: Screen failures may be re-screened once upon SPONSOR’s or CRO’s previous approval, in accordance with the Protocol. Re-screening will be reimbursed according to actual procedures performed, based on the individual item costs outlined in the below attached Detailed Budget. Payment will be made electronically within forty-five (45) days of receipt, review and approval of the invoice and will be validated on completed info verified and entered in the electronic case report form or supporting documentation, as applicable.</p> | <p>RE-SCREENING: I fallimenti dello screening possono essere ricontrattati solo previa approvazione del Promotore o della CRO, in conformità con il Protocollo. Il Re-Screening sarà rimborsato secondo le procedure effettivamente eseguite, basandosi sui costi dei singoli elementi indicati nel Budget Dettagliato allegato qui sotto. Il pagamento sarà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni completate verificate e inserite nell’electronic case report form o nella documentazione di supporto, se applicabile.</p> |
| <p>SUBJECT REIMBURSEMENT: Reasonable patient’s expenses during the Study will be reimbursed.</p> <p>Subject reimbursement will be managed and paid directly through CRO/SPONSOR third-party vendor (hereinafter “Vendor”) and will not be considered part of the Study Subject payments made to payee.</p> <p>The reimbursement will be managed as follows: any travel organized independently by the patient and any costs, such as meals, parking, and mileage, will be reimbursed by Institution directly to the patient. Namely, the Vendor pays to Institution, and Institution reimburses the patient. Institution will be required to complete a form (which contains no patient information, except for the patient ID, number, and date of visits) and will be responsible for retaining the corresponding receipts.</p> <p>It is hereby noted that the Vendor will not be required to manage patient travel arrangements and that the Vendor will therefore not in any way come into possession of the patients' identifying data.</p> <p>The patient reimbursement needs to be reflected in the informed consent form. In the event that there is a conflict between the informed consent form and this Agreement, the informed consent form shall govern and control in all matters relating to Subject reimbursement. In case reimbursement is managed by</p> | <p>RIMBORSO DEL SOGGETTO: Saranno rimborsate le spese di viaggio ragionevoli sostenute dal paziente durante lo Studio.</p> <p>Il rimborso del Soggetto sarà gestito e pagato direttamente tramite il fornitore terzo di CRO/Promotore (qui di seguito “Fornitore”) e non sarà considerato parte dei pagamenti effettuati dal Soggetto dello Studio all’Ente.</p> <p>Il rimborso avverrà come segue: qualsiasi viaggio organizzato dal paziente in autonomia e qualsiasi costo come pasti, parcheggio e chilometraggio verrà rimborsato dall’Ente direttamente al paziente, ovvero: il Fornitore paga l’Ente, l’Ente rimborsa il paziente. L’Ente sarà tenuto alla compilazione di un form (che non contiene informazioni sul paziente, ad eccezione del codice identificativo del paziente, del numero e della data delle visite), e sarà responsabile della conservazione delle ricevute corrispondenti.</p> <p>Si precisa che al Fornitore non verrà richiesto di gestire l'organizzazione dei viaggi dei pazienti e che lo stesso non entrerà quindi in alcun modo in possesso dei dati identificativi dei pazienti.</p> <p>Il rimborso del paziente deve essere indicato nel modulo di consenso informato. In caso di conflitto tra il modulo di consenso informato e il presente Contratto, il modulo di consenso informato prevarrà e prevarrà per tutte le questioni relative al rimborso del Soggetto. Nel caso in cui il rimborso sia gestito</p> |

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| <p>Institution, any request for reimbursement of Subject travel that exceeds the per visit amount set out in the Detailed Budget requires the prior written approval of the CRO and/or Sponsor on case by case basis.</p> | <p>dall'Ente, qualsiasi richiesta di rimborso per le spese di viaggio del Soggetto che superi l'importo per visita indicato nel Budget Dettagliato richiede la previa approvazione scritta della CRO e/o del Promotore, caso per caso.</p> |
| <p>UNSCHEDULED VISIT: Unscheduled visits performed as part of the Study that are outside of the normal standard of patient care and visit schedule will be reimbursed according to actual procedures performed, based on the individual item costs outlined on the below-attached Detailed Budget, upon entry of complete information into EDC and CRO's receipt of an undisputed, detailed, itemized invoice.</p> | <p>VISITA NON PROGRAMMATA: le visite non programmate eseguite come parte dello Studio che sono al di fuori del normale standard di cura del paziente e del programma delle visite saranno rimborsate in base alle effettive procedure eseguite, in base ai costi delle singole voci delineati nel Budget dettagliato allegato di seguito, a seguito dell'inserimento di informazioni complete in EDC e al ricevimento da parte della CRO di una fattura indiscussa e dettagliata.</p> |
| <p>MEDICAL CHART REVIEW FEE: The Institution will receive a payment of a medical chart review fee as outlined on the below attached Detailed Budget (which includes overhead) per chart review up to a maximum of 10 chart reviews per one (1) randomized patient, upon receipt of an undisputed invoice from Institution.. CRO reserves the right to cross-check which chart reviews have been performed using a pre-screening log, and the documented inclusion/exclusion criteria.</p> | <p>COMPENSO PER LA REVISIONE DELLA CARTELLA MEDICA: L'Ente riceverà il pagamento di una tariffa per la revisione della cartella medica come indicato nel Budget dettagliato allegato di seguito (che include le spese generali) per cartella, al ricevimento di una fattura non contestata dall'Ente fino a un massimo di 10 revisioni della cartella per un (1) paziente randomizzato. La CRO si riserva il diritto di verificare quali revisioni delle cartelle siano state eseguite utilizzando un registro di pre-screening e i criteri di inclusione/esclusione documentati.</p> |
| <p>Payee will issue one consolidated invoice at quarter end for all services performed and expenses incurred under this section during that quarter. Payment will be made electronically within forty-five (45) days of receipt, review and approval of the invoice and will be validated on completed info verified and entered in the electronic case report form or supporting documentation, as applicable.</p> | <p>Il Beneficiario emetterà una fattura consolidata alla fine del trimestre per tutti i servizi eseguiti e le spese sostenute ai sensi della presente sezione durante quel trimestre. Il pagamento verrà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni complete, verificate e inserite nel modulo elettronico o nella documentazione di supporto, a seconda dei casi.</p> |
| <p><u>5. Site Fees:</u></p> | <p><u>5. TARIFFE DEL CENTRO:</u></p> |
| <p>START-UP FEE: A one-time non-refundable start-up fee in the amount outlined in the below attached Detailed Budget will be paid to Payee for start-up related activities (e.g. preparation of regulatory documents, preparation, administration and submission of Protocol and related documents to the IRB/EC, etc.). Payment will be made upon execution of the Agreement, IRB/EC approval, and Institution</p> | <p>COMPENSO DI AVVIO: Un compenso di avvio Studio una tantum non rimborsabile per l'importo indicato nel Budget dettagliato allegato di seguito sarà pagato al Beneficiario per le attività relative all'avvio (ad esempio preparazione di documenti normativi, preparazione, amministrazione e presentazione di Protocollo e documenti correlati all'IRB/CE, ecc.). Il pagamento verrà effettuato al momento</p> |

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| activation visit, all qualifiers must be completed to receive payment. This payment is considered full and final compensation for all activities associated with Study initiation. Payment to Payee will be made upon receipt of the corresponding invoice. | dell'esecuzione del Contratto, dell'approvazione dell'IRB/CE e della visita di attivazione dell'Ente; tutte le qualificazioni dovranno essere completate per ricevere il pagamento. Questo pagamento è considerato un compenso completo e definitivo per tutte le attività associate all'inizio dello Studio. Il pagamento al Beneficiario verrà effettuato al ricevimento della fattura corrispondente. |
| All invoices for Services performed and expenses incurred under this Section will be paid within forty-five (45) days of receipt, review and approval of an invoice and will be based on completed info verified. | Tutte le fatture per i Servizi eseguiti e le spese sostenute ai sensi della presente Sezione saranno pagate entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione di una fattura e saranno basate sulle informazioni completate e verificate. |
| <u>6. Pro-Rata Payments:</u> | <u>6. Pagamenti su base proporzionale:</u> |
| Payment for Subjects who do not complete the Study may be made to Payee on a pro-rated basis. Payment will include only those Subjects who were enrolled before the premature termination of the Study or the date that notice is received of such premature termination, whichever is later. | Il pagamento per i soggetti che non completano lo Studio potrà essere effettuato al Beneficiario su base proporzionale. Il pagamento comprenderà soltanto i Soggetti arruolati prima dell'interruzione anticipata dello Studio o della data di ricevimento della notifica avente per oggetto tale interruzione anticipata, a seconda di quale situazione si verifichi per ultima. |
| Should SPONSOR terminate the Study prior to completion, pro-rated expenses and fees shall be paid as set forth in Section 3 for each Subject visit performed before the premature termination of the Study or the date notice is received of such premature termination, whichever is later. | Laddove il Promotore termini lo studio prima del suo completamento, le spese e i costi su base proporzionale saranno liquidati nei termini previsti dalla Sezione 3 per ogni visita del soggetto eseguita prima dell'interruzione anticipata dello studio o della data di ricezione dell'avviso di tale interruzione anticipata, a seconda di quale situazione si verifichi per ultima. |
| If other non-cancelable costs are incurred by Institution in accordance with the Agreement, written justification must be provided to SPONSOR for review and approval, and payment of such costs is subject to SPONSOR's approval | Laddove vengano sostenuti altri costi non cancellabili dall'Ente, in conformità al Contratto, sarà necessario fornire una giustificazione scritta al Promotore, per l'esame e l'approvazione, e il pagamento di detti costi sarà soggetto all'approvazione del Promotore. |
| In any instance where the Payee has been received unearned funds, such funds shall be returned to CRO within forty-five (45) days of notification. | In tutti i casi, qualora il Beneficiario dovesse ricevere finanziamenti non giustificati, tali fondi dovranno essere restituiti alla CRO entro quarantacinque (45) giorni dal relativo avviso. |
| <u>7. Protocol Violators</u> | <u>7. Soggetti che violano il Protocollo</u> |
| Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the | I pagamenti per i Soggetti in Studio che si ritenga abbiano violato il Protocollo possono essere esigibili |

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| point that the violation occurred at the discretion of SPONSOR. | fino al punto in cui si sia verificata la violazione, a discrezione del Promotore. |
| <u>8. Invoices</u> | <u>8. Fatture</u> |
| <p>Correct Valid Invoices should be addressed/issued to:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany VAT #DE 811138149</p> <p>Payment agent: PAREXEL International (IRL) Limited</p> <p>Preferred method of invoice submission is through CRO's self-service Site Pay Portal (hereinafter "Portal"). Payee will receive instructions on how to access and register to the Portal once Detailed Budget is set up in the Portal.</p> <p>In case Payee is not able to submit invoice through the Portal, correct valid invoices should be e-mailed to sitepaymentinvoicing@parexel.com PAREXEL Study no.: 284641</p> <p>with the following details:</p> <ul style="list-style-type: none"> • Protocol number or CRO project number shall be indicated in the subject line of the email. • Protocol number /CRO project number, Investigator name, site name and invoice number shall be indicated in the body of the email. <p>Paper invoices can be sent to: Sponsor Boehringer Ingelheim International GmbH, c/o PAREXEL International (IRL) Limited One Park Place Block C 1ST floor Upper Hatch Street Dublin 2 D02 E762 Ireland</p> <p>Parexel Study no.: 284641</p> | <p>Le fatture valide corrette devono essere intestate a:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germania P.IVA #DE 811138149</p> <p>Agente di pagamento: PAREXEL International (IRL) Limited</p> <p>Il metodo preferito per l'invio delle fatture è tramite il Portale di Pagamento Self-Service per i centri della CRO (di seguito "Portale"). Il beneficiario riceverà istruzioni su come accedere e registrarsi al "Portale" una volta che il Budget Dettagliato sarà configurato nel Portale. Nel caso in cui il beneficiario non sia in grado di presentare la fattura tramite il "Portale", le fatture corrette e valide dovranno essere inviate via e-mail a: sitepaymentinvoicing@parexel.com Studio PAREXEL n.: 284641</p> <p>con i seguenti dettagli:</p> <ul style="list-style-type: none"> . il numero di protocollo o il numero di progetto CRO devono essere indicati nell'oggetto dell'e-mail . il numero di protocollo / numero di progetto CRO / nome dello Sperimentatore / nome del centro e numero di fattura devono essere indicati nel corpo dell'e-mail <p>Le fatture cartacee possono essere intestate a: Sponsor Boehringer Ingelheim International GmbH, c/o PAREXEL International (IRL) Limited One Park Place Block C 1ST floor Upper Hatch Street Dublin 2 D02 E762 Ireland</p> <p>Studio PAREXEL n.: 284641</p> |
| All invoices must contain the following information: | Tutte le fatture dovranno contenere le seguenti informazioni: |

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| <ul style="list-style-type: none"> (a) Protocol Number (b) Invoice Number (c) Invoice Date (d) Place, Date & Description of Services Provided (e) CRO Project Number (f) Total amount payable (g) Exchange rate used (where applicable) (h) Investigator Name (i) Site Number (j) Investigator National Provider Identification (NPI) Number (k) Payee Name and Address (per this Agreement) (l) Date of Supply | <ul style="list-style-type: none"> (a) Numero di Protocollo (b) Numero di fattura (c) Data della fattura (d) Luogo, data e descrizione dei servizi forniti (e) Numero del progetto della CRO (f) Importo totale dovuto (g) Tasso di cambio utilizzato (ove pertinente) (h) Nome dello Sperimentatore (i) Numero del centro (j) Codice identificativo del fornitore nazionale (NPI) dello Sperimentatore (k) Nome e indirizzo del Beneficiario (indicati nel presente Contratto) (l) Data della fornitura |
| <p>Invoices and associated documentation should be de-identified of Subject personal information (e.g. name, date of birth, initials, etc.) prior to being submitted to CRO.</p> | <p>Le fatture e la documentazione associata devono essere private delle informazioni personali dei pazienti (per es. nome, data di nascita, iniziali, ecc.) prima di essere trasmesse alla CRO</p> |
| <p><u>9. Final Payment</u></p> | <p><u>9. Pagamento finale</u></p> |
| <p>Notwithstanding the foregoing, the final payment shall be made upon the completion of the following activities:</p> <ul style="list-style-type: none"> (a) all required Subject visits have been completed (b) SPONSOR has received all Subject data in a form suitable for analysis (c) all data clarification queries have been resolved to SPONSOR's satisfaction (d) SPONSOR has verified that all required regulatory documentation is complete (e) Institution has returned all required equipment, drugs and other material (f) the Study close-out visit has been completed | <p>Fermo restando quanto precede, il pagamento finale sarà liquidato al completamento delle seguenti attività:</p> <ul style="list-style-type: none"> (a) tutte le visite del soggetto previste siano state completate (b) ricezione da parte del Promotore di tutti i dati del Soggetto in formato idoneo per l'analisi (c) risoluzione di tutte le richieste di chiarimento dei dati, in maniera soddisfacente per il Promotore (d) verifica da parte del Promotore della completezza di tutta la documentazione normativa richiesta (e) restituzione da parte dell'Ente di tutti gli Strumenti, farmaci e altri materiali richiesti (f) la visita di fine Studio sia stata completata |
| <p>Payee shall have thirty (30) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with CRO.</p> | <p>Il Beneficiario avrà trenta (30) giorni di tempo dalla ricezione del pagamento finale ai sensi del presente Contratto, per identificare eventuali discrepanze e risolvere qualsiasi disputa di pagamento con la CRO.</p> |
| <p>All invoices for Study payments, as outlined herein, must be submitted to the CRO within sixty (60) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.</p> | <p>Tutte le fatture per i pagamenti dello Studio, le spese aggiuntive, come indicato nel presente, devono essere presentate alla CRO entro sessanta (60) giorni dalla</p> |

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| | visita di fine studio dell'Ente. Le fatture ricevute dopo questo termine non saranno rimborsate. |
| <u>10. TAX</u> | <u>10. IMPOSTE</u> |
| All fees and expenses in this Annex A are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable. | Tutte le commissioni e spese nel presente Allegato A sono da intendersi al netto di IVA o di qualsiasi imposta applicabile. Tutti i pagamenti sono soggetti alle ritenute alla fonte ove pertinente. |

Detailed Budget – Budget Dettagliato

Budget Information

| | | | |
|--------------------------------|-----------------|------------------|----------------|
| | Standard | Condition | Overall |
| | d | al | |
| Total Cost per Patient: | 36,016.84 | 68,383.16 | 104,400.00 |

Location: Italy
Site Type: All Site Types
Overhead Percent: 16.00%
Currency: EUR - Euro

Procedures

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | |
|-------|---|-----|----------|---------------|--------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|-------|
| | | | Quantity | | | | | | | | | | | | | | | |
| *INCO | Informed consent | Y | 1.00 | 55.00 | 55.00 | | | | | | | | | | | | | |
| *INEX | Review in-/exclusion criteria | Y | 2.00 | 30.00 | 30.00 | 30.00 | | | | | | | | | | | | |
| *DEMO | Demographics | Y | 1.00 | 25.00 | 25.00 | | | | | | | | | | | | | |
| *3322 | Medical history | Y | 1.00 | 50.00 | 50.00 | | | | | | | | | | | | | |
| *AUDI | AUDIT Interview | Y | 1.00 | 35.00 | 35.00 | | | | | | | | | | | | | |
| 99213 | Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight | Y | 1.00 | 85.00 | 85.00 | | | | | | | | | | | | | |
| 99212 | Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight | Y | 14.00 | 75.00 | | 75.00 | | | | | 75.00 | | | 75.00 | | 75.00 | | |
| *BMI* | Body Mass Index (BMI) | Y | 1.00 | 18.00 | 18.00 | | | | | | | | | | | | | |
| *MEAC | Waist and hip | Y | 33.00 | 11.00 | 11.00 | 11.00 | | 11.00 | | 11.00 | 11.00 | 11.00 | 11.00 | 11.00 | | 11.00 | | |
| 99211 | Vital signs (SBP, DBP, pulse) including weight | Y | 18.00 | 26.00 | | | | 26.00 | | 26.00 | | 26.00 | 26.00 | | | | | |
| 93000 | 12-lead ECG w/ Interpret. & Report | Y | 21.00 | 56.00 | 168.00 | 56.00 | | 56.00 | | | 56.00 | | | 56.00 | | 56.00 | | |
| *RCM* | Concomitant therapy | Y | 56.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 |
| *GADS | Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation | Y | 56.00 | 16.00 | | 32.00 | | | | | 32.00 | | | 32.00 | | 32.00 | | |
| *ADVE | All AEs/AESIs | Y | 56.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 |
| *ISRS | Check for injection site reaction | Y | 31.00 | 6.00 | | 6.00 | | 6.00 | | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 |

Procedures

| Code | Name | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | |
|-------|---|------------|------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|-------|
| *INCO | Informed consent | | | | | | | | | | | | | | | | | | | |
| *INEX | Review in-/exclusion criteria | | | | | | | | | | | | | | | | | | | |
| *DEMO | Demographics | | | | | | | | | | | | | | | | | | | |
| *3322 | Medical history | | | | | | | | | | | | | | | | | | | |
| *AUDI | AUDIT Interview | | | | | | | | | | | | | | | | | | | |
| 99213 | Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight | | | | | | | | | | | | | | | | | | | |
| 99212 | Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight | 75.00 | 75.00 | 75.00 | | 75.00 | | | | | | | | 75.00 | | | | | | |
| *BMI* | Body Mass Index (BMI) | | | | | | | | | | | | | | | | | | | |
| *MEAC | Waist and hip | 11.00 | 11.00 | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 |
| 99211 | Vital signs (SBP, DBP, pulse) including weight | | | | | | | 26.00 | | 26.00 | | 26.00 | | | | 26.00 | | | | 26.00 |
| 93000 | 12-lead ECG w/ Interpret. & Report | | | 56.00 | | 56.00 | | | | 56.00 | | | | 56.00 | | | | | | 56.00 |
| *RCM* | Concomitant therapy | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 |
| *GADS | Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation | 32.00 | 32.00 | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 |
| *ADVE | All AEs/AESIs | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 |
| *ISRS | Check for injection site reaction | 6.00 | 6.00 | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 |

Procedures

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | |
|-------|--|-----|----------|---------------|--------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|-------|
| | | | Quantity | | | | | | | | | | | | | | | | |
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | Y | 33.00 | 32.00 | 32.00 | 32.00 | | 32.00 | | 32.00 | 32.00 | 32.00 | 32.00 | 32.00 | | 32.00 | | | 32.00 |
| NC017 | Urine Collection - Urine analysis, UACR | Y | 28.00 | 10.00 | | 10.00 | | | | | 10.00 | | | 10.00 | | 10.00 | | | 10.00 |
| 99000 | Handling and shipment - Central lab | Y | 33.00 | 25.00 | 25.00 | 25.00 | | 25.00 | | 25.00 | 25.00 | 25.00 | 25.00 | 25.00 | | 25.00 | | | 25.00 |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | Y | 14.00 | 422.00 | 422.00 | | | | | | | | | 422.00 | | | | | |
| *FBRS | ELF Score | Y | 11.00 | 40.00 | | 40.00 | | | | | 40.00 | | | 40.00 | | | | | |
| 80299 | PK | Y | 18.00 | 42.00 | | 42.00 | | 42.00 | | | 42.00 | | | 42.00 | | 42.00 | | | |
| *FAST | Fast Score | Y | 14.00 | 35.00 | 35.00 | | | | | | | | | 35.00 | | | | | |
| *MELD | MELD scores | Y | 33.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | | 34.00 |
| *GADS | Assess ascites, hepatic encephalopathy | Y | 33.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | | 16.00 |
| *GADS | Liver Disease Progression - 5min evaluation | Y | 15.00 | 16.00 | | 16.00 | | | | | | | | 16.00 | | | | | 16.00 |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36 | Y | 56.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | Y | 1.00 | 82.00 | | 82.00 | | | | | | | | | | | | | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | Y | 2.00 | 28.00 | 28.00 | 28.00 | | | | | | | | | | | | | |
| 98966 | Vital status_Phone call | Y | 1.00 | 25.00 | | | | | | | | | | | | | | | |
| 99401 | Diet and physical activity counselling | Y | 30.00 | 70.00 | | 70.00 | | 70.00 | | 70.00 | 70.00 | 70.00 | 70.00 | 70.00 | | 70.00 | | | 70.00 |
| NC008 | Remote visit | Y | 23.00 | 23.00 | | | 23.00 | | 23.00 | | | | | | 23.00 | | | 23.00 | |

Per Patient Activity Totals: 1,137.00 673.00 91.00 386.00 91.00 288.00 517.00 288.00 288.00 990.00 91.00 477.00 91.00 395.00

Procedures

| Code | Name | V15_D365_C | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C |
|------------------------------|--|------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | 32.00 | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 |
| NC017 | Urine Collection - Urine analysis, UACR | 10.00 | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 |
| 99000 | Handling and shipment - Central lab | 25.00 | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | 422.00 | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 |
| *FBRS | ELF Score | 40.00 | | | 40.00 | | | | 40.00 | | | | 40.00 | | | | | | | | 40.00 |
| 80299 | PK | 42.00 | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 |
| *FAST | Fast Score | 35.00 | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 |
| *MELD | MELD scores | 34.00 | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 |
| *GADS | Assess ascites, hepatic encephalopathy | 16.00 | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 |
| *GADS | Liver Disease Progression - 5min evaluation | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | | | | | | | | | | | | | | | | | | | | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | | | | | | | | | | | | | | | | | | | | |
| 98966 | Vital status_Phone call | | | | | | | | | | | | | | | | | | | | |
| 99401 | Diet and physical activity counselling | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 |
| NC008 | Remote visit | | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | |
| Per Patient Activity Totals: | | 848.00 | 435.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 941.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 |

Procedures

| Code | Name | V35_W166_R | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total | ETD |
|------------------------------|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|--------|-----------|--------|
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | 32.00 | 32.00 | 1,056.00 | 32.00 |
| NC017 | Urine Collection - Urine analysis, UACR | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 280.00 | 10.00 |
| 99000 | Handling and shipment - Central lab | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | 25.00 | 25.00 | 825.00 | 25.00 |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | 422.00 | | 5,908.00 | 422.00 |
| *FBRS | ELF Score | | | | | | | | 40.00 | | | | | | | | 40.00 | | | | 40.00 | 40.00 | | 440.00 | 40.00 |
| 80299 | PK | | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | 42.00 | 42.00 | 756.00 | 42.00 |
| *FAST | Fast Score | | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | 35.00 | 35.00 | 490.00 | 35.00 |
| *MELD | MELD scores | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 1,122.00 | 34.00 |
| *GADS | Assess ascites, hepatic encephalopathy | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 528.00 | 16.00 |
| *GADS | Liver Disease Progression - 5min evaluation | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | 16.00 | 16.00 | 240.00 | 16.00 |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 1,736.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | | | | | | | | | | | | | | | | | | | | | | | 82.00 | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | | | | | | | | | | | | | | | | | | | | | | | 56.00 | |
| 98966 | Vital status_Phone call | | | | | | | | | | | | | | | | | | | | | | 25.00 | 25.00 | |
| 99401 | Diet and physical activity counselling | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | 70.00 | | 2,100.00 | 70.00 |
| NC008 | Remote visit | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | | | 529.00 | |
| Per Patient Activity Totals: | | 91.00 | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 990.00 | 442.00 | 22,712.00 | 990.00 |

Non Procedures

| Code | Name | OH? | Total Quantity | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
|---------------------------------------|---|-----|----------------|---------------|--------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|
| V1110 | Physician Salary - HOMA-IR, HOMA-β | Y | 45.50 | 41.00 | 82.00 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 | 41.00 | 41.00 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 | 41.00 |
| *STCO | Study Coordinator; Per Visit - data entry | Y | 45.50 | 69.00 | 138.00 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 | 69.00 | 69.00 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 | 69.00 |
| *NURS | Nurse; Per Visit | Y | 34.00 | 68.00 | 136.00 | 68.00 | | 68.00 | | 68.00 | 68.00 | 68.00 | 68.00 | 68.00 | | 68.00 | | 68.00 | 68.00 | 68.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense | Y | 30.00 | 34.00 | | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 |
| Per Patient Other Direct Cost Totals: | | | | | 356.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 212.00 | 212.00 | 212.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 212.00 | 212.00 |

Conditional

| Code | Name | OH? | Total Quantity | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
|-------|---|-----|----------------|---------------|----------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|
| 47000 | Liver biopsy | Y | 1.00 | 800.00 | 800.00 | | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | Y | 1.00 | 205.00 | 205.00 | | | | | | | | | | | | | | | |
| 74181 | MRI-PDFF | Y | 1.00 | 1,787.00 | 1,787.00 | | | | | | | | | | | | | | | |
| *GNCO | Informed Consent: DNA, Genetics | Y | 1.00 | 35.00 | 35.00 | | | | | | | | | | | | | | | |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | Y | 2.00 | 22.00 | | 22.00 | | | | | | | | | | | | | | |
| NC017 | Urine Collection - Urine pregnancy if applicable) | Y | 33.00 | 10.00 | 10.00 | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | Y | 4.00 | 29.00 | 29.00 | 29.00 | | | | | | | | 29.00 | | | | | | |
| 99000 | Preparation of sample for shipping - central lab | Y | 4.00 | 25.00 | 25.00 | 25.00 | | | | | | | | 25.00 | | | | | | |
| 88363 | Liver biopsy - archival | Y | 1.00 | 84.00 | 84.00 | | | | | | | | | | | | | | | |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | Y | 2.00 | 800.00 | | | | | | | | | | | | | | | 800.00 | |
| NC065 | Biopsy Sample Handling Simple | Y | 3.00 | 21.00 | 21.00 | | | | | | | | | | | | | | | 21.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | Y | 2.00 | 205.00 | | | | | | | | | | | | | | | | 205.00 |
| *CPC* | CTP | Y | 33.00 | 15.00 | 15.00 | 15.00 | | 15.00 | | 15.00 | 15.00 | 15.00 | 15.00 | 15.00 | | 15.00 | | 15.00 | 15.00 | 15.00 |

Non Procedures

| Code | Name | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C |
|---------------------------------------|---|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| V1110 | Physician Salary - HOMA-IR, HOMA-β | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 |
| *STCO | Study Coordinator; Per Visit - data entry | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 |
| *NURS | Nurse; Per Visit | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 |
| Per Patient Other Direct Cost Totals: | | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 |

Conditional

| Code | Name | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C |
|-------|---|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| 47000 | Liver biopsy | | | | | | | | | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | | |
| 74181 | MRI-PDF | | | | | | | | | | | | | | | | | | | | | | |
| *GNCO | Informed Consent: DNA, Genetics | | | | | | | | | | | | | | | | | | | | | | |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | | | | | | | | | | | | | | | | | | | | | | |
| NC017 | Urine Collection - Urine pregnancy if applicable) | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | | | | | | | | | | | | | | | | | | | | | | |
| 99000 | Preparation of sample for shipping - central lab | | | | | | | | | | | | | | | | | | | | | | |
| 88363 | Liver biopsy - archival | | | | | | | | | | | | | | | | | | | | | | |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | | | | | | | | | | | | | | | | | | | | | | |
| NC065 | Biopsy Sample Handling Simple | | | | | | | | | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | | |
| *CPC* | CTP | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 |

Non Procedures

| Code | Name | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47-W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total |
|---------------------------------------|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|--------|----------|
| V1110 | Physician Salary - HOMA-IR, HOMA-β | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 | 41.00 | 1,865.50 |
| *STCO | Study Coordinator; Per Visit - data entry | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 | 69.00 | 3,139.50 |
| *NURS | Nurse; Per Visit | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | 68.00 | 68.00 | 2,312.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | | 1,020.00 |
| Per Patient Other Direct Cost Totals: | | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 178.00 | 178.00 | 8,337.00 |

| ETD |
|--------|
| 41.00 |
| 69.00 |
| 68.00 |
| 178.00 |

Conditional

| Code | Name | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47-W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total |
|-------|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|--------|----------|
| 47000 | Liver biopsy | | | | | | | | | | | | | | | | | | | 800.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | 205.00 |
| 74181 | MRI-PDFF | | | | | | | | | | | | | | | | | | | 1,787.00 |
| *GNCO | Informed Consent: DNA, Genetics | | | | | | | | | | | | | | | | | | | 35.00 |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | | | | | | | | | | | | | | | | | 22.00 | | 44.00 |
| NC017 | Urine Collection - Urine pregnancy if applicable) | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 330.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, Nab samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | | | | | | | | | | | | | | | | | 29.00 | | 116.00 |
| 99000 | Preparation of sample for shipping - central lab | | | | | | | | | | | | | | | | | 25.00 | | 100.00 |
| 88363 | Liver biopsy - archival | | | | | | | | | | | | | | | | | | | 84.00 |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | | | | | | | | | | | | | | | | | 800.00 | | 1,600.00 |
| NC065 | Biopsy Sample Handling Simple | | | | | | | | | | | | | | | | | 21.00 | | 63.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | 205.00 | | 410.00 |
| *CPC* | CTP | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | 15.00 | 15.00 | 495.00 |

| ETD |
|----------|
| 800.00 |
| 205.00 |
| 1,787.00 |
| 35.00 |
| 22.00 |
| 10.00 |
| 29.00 |
| 25.00 |
| 84.00 |
| 800.00 |
| 21.00 |
| 205.00 |
| 15.00 |

Conditional

| Code | Name | OH? | Total Quantity | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
|----------|---|-----|----------------|---------------|-------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | Y | 20.00 | 1,892.00 | | | | | | | | | | | | | | | | |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | Y | 11.00 | 384.00 | | | | | | | | | | | | | | | | |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | Y | 11.00 | 101.00 | | | | | | | | | | | | | | | | |
| 92012 | Eye examination | Y | 8.00 | 70.00 | 70.00 | | | | | | | | | 70.00 | | | | | | |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | Y | 16.00 | 18.00 | | 18.00 | | | | | 18.00 | | | 18.00 | | | | | 18.00 | 18.00 |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | Y | 15.00 | 23.00 | | 23.00 | | | | | 23.00 | | | 23.00 | | | | | | 23.00 |
| *SF36 | SF-36 (only in case of paper questionnaires) | Y | 15.00 | 19.00 | | 19.00 | | | | | 19.00 | | | 19.00 | | | | | | 19.00 |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | Y | 29.00 | 18.00 | 18.00 | 36.00 | | | | | 18.00 | | | 18.00 | | 18.00 | | | 18.00 | 18.00 |
| *CSSR | C-SSRS (only in case of paper questionnaires) | Y | 57.00 | 52.00 | 52.00 | 104.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with T2DM) | Y | 2.00 | 37.00 | 37.00 | 37.00 | | | | | | | | | | | | | | |
| *RPMD | Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM) | Y | 53.00 | 31.00 | | | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | Y | 33.00 | 22.00 | 22.00 | 22.00 | | 22.00 | | 22.00 | 22.00 | 22.00 | 22.00 | 22.00 | | 22.00 | | | 22.00 | 22.00 |
| 80053 | clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen) | Y | 33.00 | 45.00 | 45.00 | 45.00 | | 45.00 | | 45.00 | 45.00 | 45.00 | 45.00 | 45.00 | | 45.00 | | | 45.00 | 45.00 |

Conditional

| Code | Name | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | V37_W180_R | |
|----------|---|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | |
| 92012 | Eye examination | | 70.00 | | | | | | | | 70.00 | | | | | | | | 70.00 | | | | |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | |
| *SF36 | SF-36 (only in case of paper questionnaires) | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 |
| *CSSR | C-SSRS (only in case of paper questionnaires) | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with T2DM) | | | | | | | | | | | | | | | | | | | | | | |
| *RPMD | Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM) | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 |
| 80053 | clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen) | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 |

Conditional

| Code | Name | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total | ETD |
|----------|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|-----------|----------|--------|
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 37,840.00 | 1,892.00 | |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | 384.00 | | 4,224.00 | 384.00 |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | 101.00 | | 1,111.00 | 101.00 |
| 92012 | Eye examination | | | | | 70.00 | | | | | | | | 70.00 | | | | | 70.00 | | 560.00 | 70.00 |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | 18.00 | | 288.00 | 18.00 |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | 23.00 | | 345.00 | 23.00 |
| *SF36 | SF-36 (only in case of paper questionnaires) | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | 19.00 | | 285.00 | 19.00 |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | 18.00 | 18.00 | 522.00 | 18.00 |
| *CSSR | C-SSRS (only in case of paper questionnaires) | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 2,964.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with T2DM) | | | | | | | | | | | | | | | | | | | | 74.00 | |
| *RPMd | Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM) | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | | 1,643.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | 22.00 | 22.00 | 726.00 | 22.00 |
| 80053 | clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen) | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | 45.00 | 45.00 | 1,485.00 | 45.00 |

Conditional

| Code | Name | OH? | Total Quantity | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R |
|---------------------------------|---|-----|----------------|---------------|----------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|-----------|
| 82150 | Clinical chemistry - Amylase (local lab) | Y | 33.00 | 8.00 | 8.00 | 8.00 | | 8.00 | | 8.00 | 8.00 | 8.00 | 8.00 | 8.00 | | 8.00 | | 8.00 | 8.00 | 8.00 | |
| 83690 | Clinical chemistry - Lipase (local lab) | Y | 33.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | |
| 80299 | Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure | Y | | 42.00 | | | | | | | | | | | | | | | | | |
| *SAEA | All SAEs - per occurrence | Y | | 19.00 | | | | | | | | | | | | | | | | | |
| 74150 | CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 919.00 | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 253.00 | | | | | | | | | | | | | | | | | |
| 74160 | CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 1,144.00 | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 253.00 | | | | | | | | | | | | | | | | | |
| 74181 | MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 1,787.00 | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 419.00 | | | | | | | | | | | | | | | | | |
| N74182 | MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 1,622.00 | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein) | Y | | 419.00 | | | | | | | | | | | | | | | | | |
| NC008 | Remote visit (EoS Visit via remote visits (if allowed per local regulations)) | Y | 1.00 | 23.00 | | | | | | | | | | | | | | | | | |
| Per Patient Conditional Totals: | | | | | 3,279.00 | 429.00 | 83.00 | 199.00 | 83.00 | 199.00 | 277.00 | 199.00 | 199.00 | 401.00 | 83.00 | 217.00 | 83.00 | 235.00 | 1,285.00 | 217.00 | 83.00 |

Conditional

| Code | Name | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C |
|---------------------------------|---|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| 82150 | Clinical chemistry - Amylase (local lab) | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 |
| 83690 | Clinical chemistry - Lipase (local lab) | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 |
| 80299 | Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure | | | | | | | | | | | | | | | | | | | | | |
| *SAEA | All SAEs - per occurrence | | | | | | | | | | | | | | | | | | | | | |
| 74150 | CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74160 | CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74181 | MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| N74182 | MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | |
| NC008 | Remote visit (EoS Visit via remote visits (if allowed per local regulations)) | | | | | | | | | | | | | | | | | | | | | |
| Per Patient Conditional Totals: | | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 |

Patient Cost For Standard Items

| | Screening | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
|--|-----------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|-----------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 1,493.00 | 885.00 | 146.00 | 598.00 | 146.00 | 500.00 | 729.00 | 500.00 | 500.00 | 1,202.00 | 146.00 | 689.00 | 146.00 | 607.00 | 1,060.00 | 647.00 | 146.00 |
| Overhead at 16% | 238.88 | 141.60 | 23.36 | 95.68 | 23.36 | 80.00 | 116.64 | 80.00 | 80.00 | 192.32 | 23.36 | 110.24 | 23.36 | 97.12 | 169.60 | 103.52 | 23.36 |
| Selected Cost Per Visit | 1,731.88 | 1,026.60 | 169.36 | 693.68 | 169.36 | 580.00 | 845.64 | 580.00 | 580.00 | 1,394.32 | 169.36 | 799.24 | 169.36 | 704.12 | 1,229.60 | 750.52 | 169.36 |

Patient Cost For Conditional Items

| | Screening | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
|--|-----------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|-----------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 3,279.00 | 429.00 | 83.00 | 199.00 | 83.00 | 199.00 | 277.00 | 199.00 | 199.00 | 401.00 | 83.00 | 217.00 | 83.00 | 235.00 | 1,285.00 | 217.00 | 83.00 |
| Overhead at 16% | 524.64 | 68.64 | 13.28 | 31.84 | 13.28 | 31.84 | 44.32 | 31.84 | 31.84 | 64.16 | 13.28 | 34.72 | 13.28 | 37.60 | 205.60 | 34.72 | 13.28 |
| Selected Cost Per Visit | 3,803.64 | 497.64 | 96.28 | 230.84 | 96.28 | 230.84 | 321.32 | 230.84 | 230.84 | 465.16 | 96.28 | 251.72 | 96.28 | 272.60 | 1,490.60 | 251.72 | 96.28 |

Overall Patient Cost

| | Screening | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
|--|-----------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|-----------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 4,772.00 | 1,314.00 | 229.00 | 797.00 | 229.00 | 699.00 | 1,006.00 | 699.00 | 699.00 | 1,603.00 | 229.00 | 906.00 | 229.00 | 842.00 | 2,345.00 | 864.00 | 229.00 |
| Overhead at 16% | 763.52 | 210.24 | 36.64 | 127.52 | 36.64 | 111.84 | 160.96 | 111.84 | 111.84 | 256.48 | 36.64 | 144.96 | 36.64 | 134.72 | 375.20 | 138.24 | 36.64 |
| Selected Cost Per Visit | 5,535.52 | 1,524.24 | 265.64 | 924.52 | 265.64 | 810.84 | 1,166.96 | 810.84 | 810.84 | 1,859.48 | 265.64 | 1,050.96 | 265.64 | 976.72 | 2,720.20 | 1,002.24 | 265.64 |

Patient Cost For Standard Items

| | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,153.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | |
| Overhead at 16% | 192.32 | 23.36 | 86.72 | 23.36 | 184.48 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | |
| Selected Cost Per Visit | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,337.48 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | |

Patient Cost For Conditional Items

| | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | |
| Overhead at 16% | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 435.84 | 13.28 | |
| Selected Cost Per Visit | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | 96.28 | |

Overall Patient Cost

| | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt | Treatme nt |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,807.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | 229.00 | |
| Overhead at 16% | 628.16 | 36.64 | 424.16 | 36.64 | 609.12 | 36.64 | 424.16 | 36.64 | 628.16 | 36.64 | 424.16 | 36.64 | 602.72 | 36.64 | 424.16 | 36.64 | 628.16 | 36.64 | |
| Selected Cost Per Visit | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,416.12 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | 265.64 | |

Patient Cost For Standard Items

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Follow Up | Total |
|---------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|-----------|
| | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 1,168.00 | 620.00 | 31,049.00 |
| Overhead at 16% | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 186.88 | 99.20 | 4,967.84 |
| Selected Cost Per Visit | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 1,354.88 | 719.20 | 36,016.84 |

| Discontinu ation |
|---------------------|
| ETD |
| 1,168.00 |
| 186.88 |
| 1,354.88 |

Patient Cost For Conditional Items

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Follow Up | Total |
|---------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|-----------|
| | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 3,826.00 | 209.00 | 58,951.00 |
| Overhead at 16% | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 612.16 | 33.44 | 9,432.16 |
| Selected Cost Per Visit | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 4,438.16 | 242.44 | 68,383.16 |

| Discontinu ation |
|---------------------|
| ETD |
| 3,826.00 |
| 612.16 |
| 4,438.16 |

Overall Patient Cost

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Follow Up | Total |
|---------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|--------------|------------|
| | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 2,651.00 | 229.00 | 3,767.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 4,994.00 | 829.00 | 90,000.00 |
| Overhead at 16% | 424.16 | 36.64 | 602.72 | 36.64 | 424.16 | 36.64 | 628.16 | 36.64 | 424.16 | 36.64 | 602.72 | 36.64 | 424.16 | 36.64 | 628.16 | 36.64 | 424.16 | 36.64 | 602.72 | 799.04 | 132.64 | 14,400.00 |
| Selected Cost Per Visit | 3,075.16 | 265.64 | 4,369.72 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 5,793.04 | 961.64 | 104,400.00 |

| Discontinu ation |
|---------------------|
| ETD |
| 4,994.00 |
| 799.04 |
| 5,793.04 |

Site Level Other Direct Costs

| Code | Name | OH? | Total Quantity | SITE Cost |
|--------|---|-----|----------------|--|
| #1124 | Study Fee: Set-Up; Fixed | N | 1.00 | 2,000.00 |
| *CHARC | Chart Review Fee; Per Chart | N | 1.00 | 25.00 |
| | Pharmacy Set Up fee | N | 1 | 500 |
| | Pharmacy SIV Amount | N | 1 | 150 (210) € |
| | Amount for each drug supply | N | 1 | 50 per each supply |
| | Randomization | N | 1 | 28 each patient |
| | IWRS assignment and delivery of drugs to the enrolled subject | N | 1 | 31 each dispensing |
| | supply of drugs to the enrolled subject | N | 1 | 34 each dispensing |
| | Monitoring visit | N | 1 | 100 each monitoring visit |
| | Remote Monitoring visit | N | 1 | 130 each monitoring visit |
| | drug disposal on site | N | 1 | 55 |
| | Pharmacy close out visit | N | 1 | 150 (210) € |
| | preparation of the drug to be returned | N | 1 | 50 each prepared package and for each thermostatic container |
| | Assignment, preparation and deliver of infusion drugs | N | 1 | 100 Every bag, syringe produced |
| | preparation and delivery of infusion drugs | N | 1 | 95 Every bag, syringe produced |
| | Drug dispensing to patients via courier | N | 1 | 60 Each packaging |
| | Labeling | N | 1 | 3 Each dispensing |
| | Pre-screening | N | 1.00 | 994.93 |
| | Patient Reimbursement, Per Pre-Screening Visit (a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed) | N | 1.00 | 33.00 |

The figures in brackets refer to the cost of activities carried out remotely
 Only the activities actually carried out reported by the pharmacist and with a separate invoice will be invoiced

Sotto-Studio (applicabile solo se l'Ente viene selezionato per partecipare al sottostudio e applicabile solo ai pazienti che partecipano al sottostudio) – Sub-Study (only applicable if Institution should be selected to participate in the sub-study, and only applicable to patients partaking in the sub-study)

Budget Information

Standard Condition Overall
 Total Cost per Patient: 36,060.92 94,050.48 130,111.40

Location: Italy
 Site Type: All Site Types
 Overhead Percent: 16.00%
 Currency: EUR - Euro

Procedures

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C | V17_W60_R |
|-------|---|-----|----------|---------------|--------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|-----------|
| | | | Quantity | | | | | | | | | | | | | | | | | | |
| *INCO | Informed consent | Y | 1.00 | 55.00 | 55.00 | | | | | | | | | | | | | | | | |
| *INEX | Review in-/exclusion criteria | Y | 2.00 | 30.00 | 30.00 | 30.00 | | | | | | | | | | | | | | | |
| *DEMO | Demographics | Y | 1.00 | 25.00 | 25.00 | | | | | | | | | | | | | | | | |
| *3322 | Medical history | Y | 1.00 | 50.00 | 50.00 | | | | | | | | | | | | | | | | |
| *AUDI | AUDIT Interview | Y | 1.00 | 35.00 | 35.00 | | | | | | | | | | | | | | | | |
| 99213 | Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight | Y | 1.00 | 85.00 | 85.00 | | | | | | | | | | | | | | | | |
| 99212 | Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight | Y | 14.00 | 75.00 | | 75.00 | | | | 75.00 | | | | 75.00 | | 75.00 | | 75.00 | 75.00 | 75.00 | |
| *BMI* | Body Mass Index (BMI) | Y | 1.00 | 18.00 | 18.00 | | | | | | | | | | | | | | | | |
| *MEAC | Waist and hip | Y | 33.00 | 11.00 | 11.00 | 11.00 | | 11.00 | | 11.00 | 11.00 | 11.00 | 11.00 | 11.00 | | 11.00 | | 11.00 | 11.00 | 11.00 | |
| 99211 | Vital signs (SBP, DBP, pulse) including weight | Y | 18.00 | 26.00 | | | 26.00 | | 26.00 | | 26.00 | 26.00 | 26.00 | | | | | | | | |
| 93000 | 12-lead ECG w/ Interpret. & Report | Y | 21.00 | 56.00 | 168.00 | 56.00 | | 56.00 | | 56.00 | | | | 56.00 | | 56.00 | | | | | 56.00 |
| *RCM* | Concomitant therapy | Y | 56.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 |
| *GADS | Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation | Y | 56.00 | 16.00 | | 32.00 | | | | | 32.00 | | | 32.00 | | 32.00 | | 32.00 | 32.00 | 32.00 | |
| *ADVE | All AEs/AESIs | Y | 56.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 |
| *ISRS | Check for injection site reaction | Y | 31.00 | 6.00 | | 6.00 | | 6.00 | | 6.00 | 6.00 | 6.00 | 6.00 | 6.00 | | 6.00 | | 6.00 | 6.00 | 6.00 | |

Procedures

| Code | Name | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | |
|-------|---|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------|
| *INCO | Informed consent | | | | | | | | | | | | | | | | | | | | |
| *INEX | Review in-/exclusion criteria | | | | | | | | | | | | | | | | | | | | |
| *DEMO | Demographics | | | | | | | | | | | | | | | | | | | | |
| *3322 | Medical history | | | | | | | | | | | | | | | | | | | | |
| *AUDI | AUDIT Interview | | | | | | | | | | | | | | | | | | | | |
| 99213 | Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight | | | | | | | | | | | | | | | | | | | | |
| 99212 | Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight | 75.00 | | | | | | | | 75.00 | | | | | | | | | | 75.00 | |
| *BMI* | Body Mass Index (BMI) | | | | | | | | | | | | | | | | | | | | |
| *MEAC | Waist and hip | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | | 11.00 | |
| 99211 | Vital signs (SBP, DBP, pulse) including weight | | | 26.00 | | 26.00 | | 26.00 | | 26.00 | | 26.00 | | 26.00 | | 26.00 | | 26.00 | | 26.00 | |
| 93000 | 12-lead ECG w/ Interpret. & Report | 56.00 | | | | 56.00 | | | | 56.00 | | | | 56.00 | | | | | 56.00 | | |
| *RCM* | Concomitant therapy | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 | 20.00 |
| *GADS | Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | |
| *ADVE | All AEs/AESIs | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 | 17.00 |
| *ISRS | Check for injection site reaction | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | | 6.00 | |

Procedures

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C |
|------------------------------|--|-----|----------|---------------|----------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|
| | | | Quantity | | | | | | | | | | | | | | | | |
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | Y | 33.00 | 32.00 | 32.00 | 32.00 | | 32.00 | | 32.00 | 32.00 | 32.00 | 32.00 | 32.00 | | 32.00 | | 32.00 | 32.00 |
| NC017 | Urine Collection - Urine analysis, UACR | Y | 28.00 | 10.00 | | 10.00 | | | | | 10.00 | | | 10.00 | | 10.00 | | 10.00 | 10.00 |
| 99000 | Handling and shipment - Central lab | Y | 33.00 | 25.00 | 25.00 | 25.00 | | 25.00 | | 25.00 | 25.00 | 25.00 | 25.00 | 25.00 | | 25.00 | | 25.00 | 25.00 |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | Y | 14.00 | 422.00 | 422.00 | | | | | | | | | 422.00 | | | | | 422.00 |
| *FBRS | ELF Score | Y | 11.00 | 40.00 | | 40.00 | | | | | 40.00 | | | 40.00 | | | | | 40.00 |
| 80299 | PK | Y | 18.00 | 42.00 | | 42.00 | | 42.00 | | | 42.00 | | | 42.00 | | 42.00 | | | 42.00 |
| *FAST | Fast Score | Y | 14.00 | 35.00 | 35.00 | | | | | | | | | 35.00 | | | | | 35.00 |
| *MELD | MELD scores | Y | 33.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | 34.00 | 34.00 |
| *GADS | Assess ascites, hepatic encephalopathy | Y | 33.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 |
| *GADS | Liver Disease Progression - 5min evaluation | Y | 15.00 | 16.00 | | 16.00 | | | | | | | | 16.00 | | | | | 16.00 |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36 | Y | 56.00 | 31.00 | 31.00 | 31.00 | | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | Y | 1.00 | 82.00 | | 82.00 | | | | | | | | | | | | | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | Y | 2.00 | 28.00 | 28.00 | 28.00 | | | | | | | | | | | | | |
| 98966 | Vital status_Phone call | Y | 1.00 | 25.00 | | | | | | | | | | | | | | | |
| 99401 | Diet and physical activity counselling | Y | 30.00 | 70.00 | | 70.00 | | 70.00 | | 70.00 | 70.00 | 70.00 | 70.00 | 70.00 | | 70.00 | | 70.00 | 70.00 |
| NC008 | Remote visit | Y | 23.00 | 23.00 | | | 23.00 | | 23.00 | | | | | | 23.00 | | 23.00 | | |
| *RNCO | Re-consent Process, per patient - for MRI substudy | Y | 1.00 | 38.00 | 38.00 | | | | | | | | | | | | | | |
| Per Patient Activity Totals: | | | | | 1,175.00 | 673.00 | 91.00 | 386.00 | 91.00 | 288.00 | 517.00 | 288.00 | 288.00 | 990.00 | 91.00 | 477.00 | 91.00 | 395.00 | 848.00 |

Procedures

| Code | Name | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R |
|------------------------------|--|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | |
| NC017 | Urine Collection - Urine analysis, UACR | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | |
| 99000 | Handling and shipment - Central lab | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | |
| *FBRS | ELF Score | | | 40.00 | | | | 40.00 | | | | 40.00 | | | | 40.00 | | | | 40.00 | |
| 80299 | PK | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | |
| *FAST | Fast Score | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | |
| *MELD | MELD scores | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | |
| *GADS | Assess ascites, hepatic encephalopathy | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | |
| *GADS | Liver Disease Progression - 5min evaluation | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | | | | | | | | | | | | | | | | | | | | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | | | | | | | | | | | | | | | | | | | | |
| 98966 | Vital status_Phone call | | | | | | | | | | | | | | | | | | | | |
| 99401 | Diet and physical activity counselling | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | |
| NC008 | Remote visit | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 |
| *RNCO | Re-consent Process, per patient - for MRI substudy | | | | | | | | | | | | | | | | | | | | |
| Per Patient Activity Totals: | | 435.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 941.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 |

Procedures

| Code | Name | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total | ETD |
|------------------------------|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|--------|-----------|--------|
| NC011 | Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | | 32.00 | 32.00 | 32.00 | 1,056.00 | 32.00 |
| NC017 | Urine Collection - Urine analysis, UACR | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 280.00 | 10.00 |
| 99000 | Handling and shipment - Central lab | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | | 25.00 | 25.00 | 25.00 | 825.00 | 25.00 |
| 91200 | Fibroscan: (VCTE - LSM) and CAP) | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | | | | 422.00 | 422.00 | | 5,908.00 | 422.00 |
| *FBRS | ELF Score | | | | | | | 40.00 | | | | | | | | 40.00 | | | | | 40.00 | | 440.00 | 40.00 |
| 80299 | PK | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | | | | 42.00 | 42.00 | 42.00 | 756.00 | 42.00 |
| *FAST | Fast Score | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | | | | 35.00 | 35.00 | 35.00 | 490.00 | 35.00 |
| *MELD | MELD scores | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 1,122.00 | 34.00 |
| *GADS | Assess ascites, hepatic encephalopathy | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 528.00 | 16.00 |
| *GADS | Liver Disease Progression - 5min evaluation | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | | | | 16.00 | 16.00 | 16.00 | 240.00 | 16.00 |
| *RPMD | eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD-NASH, PHQ-9, C-SSRS, SF36 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 1,736.00 | 31.00 |
| 98960 | Training in/observe pre-filled syringe administration | | | | | | | | | | | | | | | | | | | | | | 82.00 | |
| *DPSD | Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials | | | | | | | | | | | | | | | | | | | | | | 56.00 | |
| 98966 | Vital status_Phone call | | | | | | | | | | | | | | | | | | | | | 25.00 | 25.00 | |
| 99401 | Diet and physical activity counselling | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | | 70.00 | 70.00 | 70.00 | 2,100.00 | 70.00 |
| NC008 | Remote visit | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | 23.00 | | | | 529.00 | |
| *RNCO | Re-consent Process, per patient - for MRI substudy | | | | | | | | | | | | | | | | | | | | | | 38.00 | |
| Per Patient Activity Totals: | | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 91.00 | 330.00 | 91.00 | 990.00 | 91.00 | 330.00 | 91.00 | 901.00 | 990.00 | 442.00 | 22,750.00 | 990.00 |

Non Procedures

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C |
|---------------------------------------|---|-----|----------|---------------|--------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|
| | | | Quantity | | | | | | | | | | | | | | | | |
| V1110 | Physician Salary - HOMA-IR, HOMA-β | Y | 45.50 | 41.00 | 82.00 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 | 41.00 | 41.00 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 |
| *STCO | Study Coordinator; Per Visit - data entry | Y | 45.50 | 69.00 | 138.00 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 | 69.00 | 69.00 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 |
| *NURS | Nurse; Per Visit | Y | 34.00 | 68.00 | 136.00 | 68.00 | | 68.00 | | 68.00 | 68.00 | 68.00 | 68.00 | 68.00 | | 68.00 | | 68.00 | 68.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU - pre-filled syringe, dispense IMP | Y | 30.00 | 34.00 | | 34.00 | | 34.00 | | 34.00 | 34.00 | 34.00 | 34.00 | 34.00 | | 34.00 | | 34.00 | 34.00 |
| Per Patient Other Direct Cost Totals: | | | | | 356.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 212.00 | 212.00 | 212.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 212.00 |

Conditional

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C |
|--------|--|-----|----------|---------------|----------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|
| | | | Quantity | | | | | | | | | | | | | | | | |
| 47000 | Liver biopsy | Y | 1.00 | 800.00 | 800.00 | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | Y | 1.00 | 205.00 | 205.00 | | | | | | | | | | | | | | |
| 74181 | MRI-PDFF | Y | 1.00 | 1,787.00 | 1,787.00 | | | | | | | | | | | | | | |
| *GNCO | Informed Consent: DNA, Genetics | Y | 1.00 | 35.00 | 35.00 | | | | | | | | | | | | | | |
| 74181 | MRI-PDFF and T1-weighted imaging | Y | 7.00 | 1,787.00 | | 1,787.00 | | | | | | | | 1,787.00 | | | | | 1,787.00 |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | Y | 2.00 | 22.00 | | 22.00 | | | | | | | | | | | | | |
| N76391 | MRE (subset of trial participants) | Y | 7.00 | 1,374.00 | | 1,374.00 | | | | | | | | 1,374.00 | | | | | 1,374.00 |
| NC017 | Urine Collection - Urine pregnancy if applicable) | Y | 33.00 | 10.00 | 10.00 | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 | | 10.00 | | 10.00 | 10.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | Y | 4.00 | 29.00 | 29.00 | 29.00 | | | | | | | | 29.00 | | | | | |
| 99000 | Preparation of sample for shipping - central lab | Y | 4.00 | 25.00 | 25.00 | 25.00 | | | | | | | | 25.00 | | | | | |

Non Procedures

| Code | Name | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C |
|---------------------------------------|---|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| V1110 | Physician Salary - HOMA-IR, HOMA-β | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 |
| *STCO | Study Coordinator; Per Visit - data entry | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 |
| *NURS | Nurse; Per Visit | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense IMP | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 |
| Per Patient Other Direct Cost Totals: | | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 |

Conditional

| Code | Name | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C |
|--------|--|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| 47000 | Liver biopsy | | | | | | | | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | |
| 74181 | MRI-PDF | | | | | | | | | | | | | | | | | | | | | |
| *GNCO | Informed Consent: DNA, Genetics | | | | | | | | | | | | | | | | | | | | | |
| 74181 | MRI-PDF and T1-weighted imaging | | | | | | | | | | 1,787.00 | | | | | | | | | | | |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | | | | | | | | | | | | | | | | | | | | | |
| N76391 | MRE (subset of trial participants) | | | | | | | | | | 1,374.00 | | | | | | | | | | | |
| NC017 | Urine Collection - Urine pregnancy if applicable) | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | | | | | | | | | | | | | | | | | | | | | |
| 99000 | Preparation of sample for shipping - central lab | | | | | | | | | | | | | | | | | | | | | |

Non Procedures

| Code | Name | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total |
|---------------------------------------|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------|--------|----------|
| V1110 | Physician Salary - HOMA-IR, HOMA-β | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 20.50 | 41.00 | 41.00 | 41.00 | 1,865.50 |
| *STCO | Study Coordinator; Per Visit + data entry | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 34.50 | 69.00 | 69.00 | 69.00 | 3,139.50 |
| *NURS | Nurse; Per Visit | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | | 68.00 | 68.00 | 68.00 | 2,312.00 |
| VPHRM | Dispensing, Simple; Per Visit - Hand out IFU - pre-filled syringe, dispense IMP | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | 34.00 | | | 1,020.00 |
| Per Patient Other Direct Cost Totals: | | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 55.00 | 212.00 | 178.00 | 178.00 | 8,337.00 |

| ETD |
|--------|
| 41.00 |
| 69.00 |
| 68.00 |
| 178.00 |

Conditional

| Code | Name | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total |
|--------|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|--------|-----------|
| 47000 | Liver biopsy | | | | | | | | | | | | | | | | | | | | | 800.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | 205.00 |
| 74181 | MRI-PDF | | | | | | | | | | | | | | | | | | | | | 1,787.00 |
| *GNCO | Informed Consent: DNA, Genetics | | | | | | | | | | | | | | | | | | | | | 35.00 |
| 74181 | MRI-PDF and T1-weighted imaging | | 1,787.00 | | | | | | | | | | | | 1,787.00 | | | | | 1,787.00 | | 12,509.00 |
| *IWQL | Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity) | | | | | | | | | | | | | | | | | | | 22.00 | | 44.00 |
| N76391 | MRE (subset of trial participants) | | 1,374.00 | | | | | | | | | | | | 1,374.00 | | | | | 1,374.00 | | 9,618.00 |
| NC017 | Urine Collection - Urine pregnancy if applicable) | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | | 10.00 | 10.00 | 10.00 | 330.00 |
| 36415 | Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit) | | | | | | | | | | | | | | | | | | | 29.00 | | 116.00 |
| 99000 | Preparation of sample for shipping - central lab | | | | | | | | | | | | | | | | | | | 25.00 | | 100.00 |

| ETD |
|----------|
| |
| |
| |
| |
| 1,787.00 |
| 22.00 |
| 1,374.00 |
| 10.00 |
| 29.00 |
| 25.00 |

Conditional

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C |
|----------|---|-----|----------|---------------|-------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|
| | | | Quantity | | | | | | | | | | | | | | | | |
| 88363 | Liver biopsy - archival | Y | 1.00 | 84.00 | 84.00 | | | | | | | | | | | | | | |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | Y | 2.00 | 800.00 | | | | | | | | | | | | | | | 800.00 |
| NC065 | Biopsy Sample Handling Simple | Y | 3.00 | 21.00 | 21.00 | | | | | | | | | | | | | | 21.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | Y | 2.00 | 205.00 | | | | | | | | | | | | | | | 205.00 |
| *CPC* | CTP | Y | 33.00 | 15.00 | 15.00 | 15.00 | | 15.00 | | 15.00 | 15.00 | 15.00 | 15.00 | 15.00 | | 15.00 | | 15.00 | 15.00 |
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | Y | 20.00 | 1,892.00 | | | | | | | | | | | | | | | |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | Y | 11.00 | 384.00 | | | | | | | | | | | | | | | |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | Y | 11.00 | 101.00 | | | | | | | | | | | | | | | |
| 92012 | Eye examination | Y | 8.00 | 70.00 | 70.00 | | | | | | | | | 70.00 | | | | | |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | Y | 16.00 | 18.00 | | 18.00 | | | | | 18.00 | | | 18.00 | | | | 18.00 | 18.00 |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | Y | 15.00 | 23.00 | | 23.00 | | | | | 23.00 | | | 23.00 | | | | | 23.00 |
| *SF36 | SF-36 (only in case of paper questionnaires) | Y | 15.00 | 19.00 | | 19.00 | | | | | 19.00 | | | 19.00 | | | | | 19.00 |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | Y | 29.00 | 18.00 | 18.00 | 36.00 | | | | | 18.00 | | | 18.00 | | 18.00 | | 18.00 | |
| *CSSR | C-SSRS (only in case of paper questionnaires) | Y | 57.00 | 52.00 | 52.00 | 104.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with | Y | 2.00 | 37.00 | 37.00 | 37.00 | | | | | | | | | | | | | |
| *RPM | Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM) | Y | 53.00 | 31.00 | | | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | Y | 33.00 | 22.00 | 22.00 | 22.00 | | 22.00 | | 22.00 | 22.00 | 22.00 | 22.00 | 22.00 | | 22.00 | | 22.00 | 22.00 |

Conditional

| Code | Name | V16_D379_C | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | |
|----------|---|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|
| 88363 | Liver biopsy - archival | | | | | | | | | | | | | | | | | | | | | |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | | | | | | | | | | | | | | | | | | | | | |
| NC065 | Biopsy Sample Handling Simple | | | | | | | | | | | | | | | | | | | | | |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | |
| *CPC* | CTP | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 |
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | | 384.00 | |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | | 101.00 | |
| 92012 | Eye examination | | | 70.00 | | | | | | | | 70.00 | | | | | | | | | | 70.00 |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | | 18.00 | |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | | 23.00 | |
| *SF36 | SF-36 (only in case of paper questionnaires) | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | | 19.00 | |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 |
| *CSSR | C-SSRS (only in case of paper questionnaires) | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with | | | | | | | | | | | | | | | | | | | | | |
| *RPMD | Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM) | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 |
| 80053 | clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen) | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 |

Conditional

| Code | Name | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | Total | ETD | |
|----------|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|--------|-------|-----------|----------|
| 88363 | Liver biopsy - archival | | | | | | | | | | | | | | | | | | | | | | 84.00 | | |
| 47000 | Liver biopsy(a triggered biopsy if clinically indicated) | | | | | | | | | | | | | | | | | | | | | 800.00 | | 1,600.00 | 800.00 |
| NC065 | Biopsy Sample Handling Simple | | | | | | | | | | | | | | | | | | | | | 21.00 | | 63.00 | 21.00 |
| 99152 | Moderate Sedation Init 15 Min 5+yrs | | | | | | | | | | | | | | | | | | | | | 205.00 | | 410.00 | 205.00 |
| *CPC* | CTP | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | | 15.00 | 15.00 | 15.00 | 15.00 | 495.00 | 15.00 |
| 91110 | UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | | 1,892.00 | 1,892.00 | | | 37,840.00 | 1,892.00 |
| 76700 | Abdominal ultrasound (only for participants who progressed to cirrhosis) | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | | | | 384.00 | 384.00 | | | 4,224.00 | 384.00 |
| 76830-26 | Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis) | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | | | | 101.00 | 101.00 | | | 1,111.00 | 101.00 |
| 92012 | Eye examination | | | | | | | 70.00 | | | | | | | | 70.00 | | | | | 70.00 | | | 560.00 | 70.00 |
| *NASH | NASH-CHECK Questionnaire (only in case of paper questionnaires) | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | | | | 18.00 | 18.00 | | | 288.00 | 18.00 |
| *CLDQ | CLDQ NAFLD-NASH (only in case of paper questionnaires) | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | | | | 23.00 | 23.00 | | | 345.00 | 23.00 |
| *SF36 | SF-36 (only in case of paper questionnaires) | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | | | | 19.00 | 19.00 | | | 285.00 | 19.00 |
| *PHQ9 | PHQ-9 (only in case of paper questionnaires) | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | | 18.00 | 18.00 | 18.00 | | 522.00 | 18.00 |
| *CSSR | C-CSSR (only in case of paper questionnaires) | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | 52.00 | | 2,964.00 | 52.00 |
| *TOHM | Hand out of SMBG device (trial participants with | | | | | | | | | | | | | | | | | | | | | | | 74.00 | |
| *RPMD | Hyper-/hypoglycaemic episode review (eDiary – participants with TZDM) | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | 31.00 | | | 1,643.00 | 31.00 |
| 85025 | haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | | 22.00 | 22.00 | 22.00 | | 726.00 | 22.00 |
| 80053 | clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen) | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | | 45.00 | 45.00 | 45.00 | | 1,485.00 | 45.00 |

Conditional

| Code | Name | OH? | Total | Selected Cost | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
|---------------------------------|---|-----|----------|---------------|----------|------------|----------|----------|----------|----------|----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|
| | | | Quantity | | | | | | | | | | | | | | | | | |
| 82150 | Clinical chemistry - Amylase (local lab) | Y | 33.00 | 8.00 | 8.00 | 8.00 | | 8.00 | | 8.00 | 8.00 | 8.00 | 8.00 | 8.00 | | 8.00 | | 8.00 | 8.00 | 8.00 |
| 83690 | Clinical chemistry - Lipase (local lab) | Y | 33.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 | 16.00 | 16.00 | | 16.00 | | 16.00 | 16.00 | 16.00 |
| 80299 | Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure | Y | | 42.00 | | | | | | | | | | | | | | | | |
| *SAEA | All SAEs - per occurrence | Y | | 19.00 | | | | | | | | | | | | | | | | |
| 74150 | CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 919.00 | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 253.00 | | | | | | | | | | | | | | | | |
| 74160 | CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 1,144.00 | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 253.00 | | | | | | | | | | | | | | | | |
| 74181 | MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 1,787.00 | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 419.00 | | | | | | | | | | | | | | | | |
| N74182 | MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 1,622.00 | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein) | Y | | 419.00 | | | | | | | | | | | | | | | | |
| NC008 | Remote visit (EoS Visit via remote visits (if allowed per local regulations)) | Y | 1.00 | 23.00 | | | | | | | | | | | | | | | | |
| Per Patient Conditional Totals: | | | | | 3,279.00 | 3,590.00 | 83.00 | 199.00 | 83.00 | 199.00 | 277.00 | 199.00 | 199.00 | 3,562.00 | 83.00 | 217.00 | 83.00 | 235.00 | 4,446.00 | 217.00 |

Conditional

| Code | Name | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | V35_W168_R | V36_W174_C | | |
|---------------------------------|---|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--|-------|
| 82150 | Clinical chemistry - Amylase (local lab) | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 | | 8.00 |
| 83690 | Clinical chemistry - Lipase (local lab) | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 | | 16.00 |
| 80299 | Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure | | | | | | | | | | | | | | | | | | | | | | |
| *SAEA | All SAEs - per occurrence | | | | | | | | | | | | | | | | | | | | | | |
| 74150 | CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74160 | CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74150-26 | CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74181 | MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| N74182 | MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| 74181-26 | MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α -fetoprotein) | | | | | | | | | | | | | | | | | | | | | | |
| NC008 | Remote visit (EoS Visit via remote visits (if allowed per local regulations)) | | | | | | | | | | | | | | | | | | | | | | |
| Per Patient Conditional Totals: | | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 5,885.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | | |

Patient Cost For Standard Items

| | Screenin g | Treatment | Treatment | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t |
|--|---------------|------------|-----------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 1,531.00 | 885.00 | 146.00 | 598.00 | 146.00 | 500.00 | 729.00 | 500.00 | 500.00 | 1,202.00 | 146.00 | 689.00 | 146.00 | 607.00 | 1,060.00 | 647.00 |
| Overhead at 16% | 244.96 | 141.60 | 23.36 | 95.68 | 23.36 | 80.00 | 116.64 | 80.00 | 80.00 | 192.32 | 23.36 | 110.24 | 23.36 | 97.12 | 169.60 | 103.52 |
| Selected Cost Per Visit | 1,775.96 | 1,026.60 | 169.36 | 693.68 | 169.36 | 580.00 | 845.64 | 580.00 | 580.00 | 1,394.32 | 169.36 | 799.24 | 169.36 | 704.12 | 1,229.60 | 750.52 |
| Cumulative Cost Per Patient | 1,775.96 | 2,802.56 | 2,971.92 | 3,665.60 | 3,834.96 | 4,414.96 | 5,260.60 | 5,840.60 | 6,420.60 | 7,814.92 | 7,984.28 | 8,783.52 | 8,952.88 | 9,657.00 | 10,886.60 | 11,637.12 |

Patient Cost For Conditional Items

| | Screenin g | Treatment | Treatment | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t |
|--|---------------|------------|-----------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 3,279.00 | 3,590.00 | 83.00 | 199.00 | 83.00 | 199.00 | 277.00 | 199.00 | 199.00 | 3,562.00 | 83.00 | 217.00 | 83.00 | 235.00 | 4,446.00 | 217.00 |
| Overhead at 16% | 524.64 | 574.40 | 13.28 | 31.84 | 13.28 | 31.84 | 44.32 | 31.84 | 31.84 | 569.92 | 13.28 | 34.72 | 13.28 | 37.60 | 711.36 | 34.72 |
| Selected Cost Per Visit | 3,803.64 | 4,164.40 | 96.28 | 230.84 | 96.28 | 230.84 | 321.32 | 230.84 | 230.84 | 4,131.92 | 96.28 | 251.72 | 96.28 | 272.60 | 5,157.36 | 251.72 |
| Cumulative Cost Per Patient | 3,803.64 | 7,968.04 | 8,064.32 | 8,295.16 | 8,391.44 | 8,622.28 | 8,943.60 | 9,174.44 | 9,405.28 | 13,537.20 | 13,633.48 | 13,885.20 | 13,981.48 | 14,254.08 | 19,411.44 | 19,663.16 |

Overall Patient Cost

| | Screenin g | Treatment | Treatment | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t |
|--|---------------|------------|-----------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | SV1 | V2_RAND_D1 | V3_D15_R | V4_D29_C | V5_D43_R | V6_D57_C | V7_D85_C | V8_D113_C | V9_D141_C | V10_D169_C | V11_D211_R | V12_D253_C | V13_D295_R | V14_D337_C | V15_D365_C | V16_D379_C |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 4,810.00 | 4,475.00 | 229.00 | 797.00 | 229.00 | 699.00 | 1,006.00 | 699.00 | 699.00 | 4,764.00 | 229.00 | 906.00 | 229.00 | 842.00 | 5,506.00 | 864.00 |
| Overhead at 16% | 769.60 | 716.00 | 36.64 | 127.52 | 36.64 | 111.84 | 160.96 | 111.84 | 111.84 | 762.24 | 36.64 | 144.96 | 36.64 | 134.72 | 880.96 | 138.24 |
| Selected Cost Per Visit | 5,579.60 | 5,191.00 | 265.64 | 924.52 | 265.64 | 810.84 | 1,166.96 | 810.84 | 810.84 | 5,526.24 | 265.64 | 1,050.96 | 265.64 | 976.72 | 6,386.96 | 1,002.24 |
| Cumulative Cost Per Patient | 5,579.60 | 10,770.60 | 11,036.24 | 11,960.76 | 12,226.40 | 13,037.24 | 14,204.20 | 15,015.04 | 15,825.88 | 21,352.12 | 21,617.76 | 22,668.72 | 22,934.36 | 23,911.08 | 30,298.04 | 31,300.28 |

Patient Cost For Standard Items

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,153.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | |
| Overhead at 16% | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 184.48 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | |
| Selected Cost Per Visit | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,337.48 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | |
| Cumulative Cost Per Patient | 11,806.48 | 13,200.80 | 13,370.16 | 13,998.88 | 14,168.24 | 15,505.72 | 15,675.08 | 16,303.80 | 16,473.16 | 17,867.48 | 18,036.84 | 18,665.56 | 18,834.92 | 20,126.00 | 20,295.36 | 20,924.08 | 21,093.44 | 22,487.76 | |

Patient Cost For Conditional Items

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 5,885.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | |
| Overhead at 16% | 13.28 | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 941.60 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 435.84 | |
| Selected Cost Per Visit | 96.28 | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 6,826.60 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | |
| Cumulative Cost Per Patient | 19,759.44 | 22,919.28 | 23,015.56 | 25,462.00 | 25,558.28 | 28,636.92 | 28,733.20 | 31,179.64 | 31,275.92 | 38,102.52 | 38,198.80 | 40,645.24 | 40,741.52 | 43,820.16 | 43,916.44 | 46,362.88 | 46,459.16 | 49,619.00 | |

Overall Patient Cost

| | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t | Treatmen t |
|--|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| | V17_W60_R | V18_W66_C | V19_W72_R | V20_W78_C | V21_W84_R | V22_W90_C | V23_W96_R | V24_W102_C | V25_W108_R | V26_W114_C | V27_W120_R | V28_W126_C | V29_W132_R | V30_W138_C | V31_W144_R | V32_W150_C | V33_W156_R | V34_W162_C | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 229.00 | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,807.00 | 229.00 | 2,651.00 | 229.00 | 7,087.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | |
| Overhead at 16% | 36.64 | 628.16 | 36.64 | 424.16 | 36.64 | 609.12 | 36.64 | 424.16 | 36.64 | 1,133.92 | 36.64 | 424.16 | 36.64 | 602.72 | 36.64 | 424.16 | 36.64 | 628.16 | |
| Selected Cost Per Visit | 265.64 | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,416.12 | 265.64 | 3,075.16 | 265.64 | 8,220.92 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | |
| Cumulative Cost Per Patient | 31,565.92 | 36,120.08 | 36,385.72 | 39,460.88 | 39,726.52 | 44,142.64 | 44,408.28 | 47,483.44 | 47,749.08 | 55,970.00 | 56,235.64 | 59,310.80 | 59,576.44 | 63,946.16 | 64,211.80 | 67,286.96 | 67,552.60 | 72,106.76 | |

Patient Cost For Standard Items

| | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Follow Up | Total |
|---------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------|-----------|
| | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 146.00 | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 146.00 | 542.00 | 146.00 | 1,202.00 | 146.00 | 542.00 | 146.00 | 1,113.00 | 1,168.00 | 620.00 | 31,087.00 |
| Overhead at 16% | 23.36 | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 23.36 | 86.72 | 23.36 | 192.32 | 23.36 | 86.72 | 23.36 | 178.08 | 186.88 | 99.20 | 4,973.92 |
| Selected Cost Per Visit | 169.36 | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 169.36 | 628.72 | 169.36 | 1,394.32 | 169.36 | 628.72 | 169.36 | 1,291.08 | 1,354.88 | 719.20 | 36,060.92 |
| Cumulative Cost Per Patient | 22,657.12 | 23,285.84 | 23,455.20 | 24,746.28 | 24,915.64 | 25,544.36 | 25,713.72 | 27,108.04 | 27,277.40 | 27,906.12 | 28,075.48 | 29,366.56 | 29,535.92 | 30,164.64 | 30,334.00 | 31,728.32 | 31,897.68 | 32,526.40 | 32,695.76 | 33,986.84 | 35,341.72 | 36,060.92 | |

| Discontinuation |
|-----------------|
| ETD |
| 1,168.00 |
| 186.88 |
| 1,354.88 |
| 37,415.80 |

Patient Cost For Conditional Items

| | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Follow Up | Total | |
|---------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------|-----------|-----------|
| | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 83.00 | 2,109.00 | 83.00 | 5,815.00 | 83.00 | 2,109.00 | 83.00 | 2,724.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 83.00 | 2,109.00 | 83.00 | 5,885.00 | 83.00 | 2,109.00 | 83.00 | 2,654.00 | 6,987.00 | 209.00 | 81,078.00 |
| Overhead at 16% | 13.28 | 337.44 | 13.28 | 930.40 | 13.28 | 337.44 | 13.28 | 435.84 | 13.28 | 337.44 | 13.28 | 424.64 | 13.28 | 337.44 | 13.28 | 941.60 | 13.28 | 337.44 | 13.28 | 424.64 | 1,117.92 | 33.44 | 12,972.48 |
| Selected Cost Per Visit | 96.28 | 2,446.44 | 96.28 | 6,745.40 | 96.28 | 2,446.44 | 96.28 | 3,159.84 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 96.28 | 2,446.44 | 96.28 | 6,826.60 | 96.28 | 2,446.44 | 96.28 | 3,078.64 | 8,104.92 | 242.44 | 94,050.48 |
| Cumulative Cost Per Patient | 49,715.28 | 52,161.72 | 52,258.00 | 59,003.40 | 59,099.68 | 61,546.12 | 61,642.40 | 64,802.24 | 64,898.52 | 67,344.96 | 67,441.24 | 70,519.88 | 70,616.16 | 73,062.60 | 73,158.88 | 79,985.48 | 80,081.76 | 82,528.20 | 82,624.48 | 85,703.12 | 93,808.04 | 94,050.48 | |

| Discontinuation |
|-----------------|
| ETD |
| 6,987.00 |
| 1,117.92 |
| 8,104.92 |
| 102,155.40 |

Overall Patient Cost

| | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Treatment t | Follow Up | Total | |
|---------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|------------|------------|------------|
| | V35_W168_R | V36_W174_C | V37_W180_R | V38_W186_C | V39_W192_R | V40_W198_C | V41_W204_R | V42_W210_C | V43_W216_R | V44_W222_C | V45_W228_R | V46_W234_C | V47_W240_R | V48_W246_C | V49_W252_R | V50_W258_C | V51_W264_R | V52_W270_C | V53_W276_R | V54_W282_C | EOT | FU/EOS | |
| Costs Not Charged with Overhead | | | | | | | | | | | | | | | | | | | | | | | |
| Costs Charged with Overhead | 229.00 | 2,651.00 | 229.00 | 6,928.00 | 229.00 | 2,651.00 | 229.00 | 3,926.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 229.00 | 2,651.00 | 229.00 | 7,087.00 | 229.00 | 2,651.00 | 229.00 | 3,767.00 | 8,155.00 | 829.00 | 112,165.00 |
| Overhead at 16% | 36.64 | 424.16 | 36.64 | 1,108.48 | 36.64 | 424.16 | 36.64 | 628.16 | 36.64 | 424.16 | 36.64 | 602.72 | 36.64 | 424.16 | 36.64 | 1,133.92 | 36.64 | 424.16 | 36.64 | 602.72 | 1,304.80 | 132.64 | 17,946.40 |
| Selected Cost Per Visit | 265.64 | 3,075.16 | 265.64 | 8,036.48 | 265.64 | 3,075.16 | 265.64 | 4,554.16 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 265.64 | 3,075.16 | 265.64 | 8,220.92 | 265.64 | 3,075.16 | 265.64 | 4,369.72 | 9,459.80 | 961.64 | 130,111.40 |
| Cumulative Cost Per Patient | 72,372.40 | 75,447.56 | 75,713.20 | 83,749.68 | 84,015.32 | 87,090.48 | 87,356.12 | 91,910.28 | 92,175.92 | 95,251.08 | 95,516.72 | 99,886.44 | 100,152.08 | 103,227.24 | 103,492.88 | 111,713.80 | 111,979.44 | 115,054.60 | 115,320.24 | 119,689.96 | 129,149.76 | 130,111.40 | |

| Discontinuation |
|-----------------|
| ETD |
| 8,155.00 |
| 1,304.80 |
| 9,459.80 |
| 139,571.20 |