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Summary information on the funding and supply of inclisiran (Leqvio®)

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1. Executive summary

- 1.1 This document describes the funding and supply arrangements for inclisiran (Leqvio®) as an option in the lipid management pathway. These arrangements follow from the recommendations set out in TA733 by NICE on 06 October 2021. An overview is provided for both primary care and secondary care.
- 1.2 This document is relevant for any healthcare professional involved in the prescribing, funding and supply of inclisiran and has been updated to include additional information on funding as well as new frequently asked questions and glossary sections.

2. Funding overview

Primary care

- 2.1 NHS England are funding inclisiran centrally from a national NHS budget in order that local finances are not a barrier to access. A 'Nominal Charge' has been agreed when general practice and community pharmacy purchase inclisiran directly from the national wholesaler (AAH) to help make inclisiran more affordable; this is the price at which they will be able to purchase the medicine and is met from the drugs budgets held by Integrated Care Boards (ICBs).
- 2.2 Inclisiran is available from the wholesaler (AAH) at £45 (Nominal Charge) plus VAT ([Health professionals and pharmaceutical products \(VAT Notice 701/57\) - GOV.UK \(www.gov.uk\)](#)). The AAH payment terms are 30 days from the end the month in which the order was placed.
- 2.3 Inclisiran is available in general practice as a personally administered item reimbursed via an FP10 prescription and is listed in the Drug Tariff (Part VIIC) at a Reimbursed Amount of £55 (£50 from 01 April 2023) per injection (the £45 Nominal Charge identified at 2.2 plus £10 (£5 from 01 April 2023)).

- 2.4 Inclisiran is listed in the Drug Tariff as a “discount is not deducted” item meaning there is no discount deduction (also known as “Clawback”) applied for pharmacy contractors to the Reimbursed Amount (£55 and £50 from 01 April 2023) listed in the Drug Tariff.
- 2.5 For general practice, inclisiran will be reimbursed at the reimbursed amount set out in the Drug Tariff. The “discount is not deducted” is not applicable to general practice, therefore, the discount deduction (“clawback”) will be deducted from the Reimbursed Amount (£55 and £50 from 01 April 2023). The level of discount deduction applied is as per Annex G of the [General Medical Services Statement of Financial Entitlements](#).
- 2.6 The cost to the Integrated Care Board (ICB) and primary care prescribing budget will be the Reimbursement Amount of £55 (£50 from 01 April 2023) set out above in 2.3. This is a set amount and is not affected by the amount a prescriber/dispenser is reimbursed following the application of clawback for Dispensing Practices.
- 2.7 As the Nominal Charge is set below the Contract Price which has been agreed with Novartis, a separate payment will be made to Novartis from a central NHS budget for the difference between the Contract price and the Nominal Price. This will not impact local budget.

Secondary care

Effective 01 January 2022, how this treatment is funded for trusts has changed

- 2.8 Inclisiran was added to the Payment by Results (PbR) excluded drug list on 01 April 2022 and is now reimbursed centrally by NHS England. NHS England shadowed this arrangement from 01 January 2022. Prior to this change (September – December 2021) trusts were charged the confidential contract price via the CAP portal when ordering stock of inclisiran and did not receive reimbursement.

- 2.9 Inclisiran used by trusts is now, as of 01 January 2022, reimbursed via the interim high cost drug cost and volume arrangements for Specialised High Cost Drugs.
- 2.10 Inclisiran is reimbursed under the cost and volume process. The NHS Standard Contract, Schedule 6a Reporting Requirements for drugs will apply. Full reimbursement will depend on the provision of accurate data submitted through existing systems, i.e. complete and accurate information in the provider's drugs patient level contract monitoring data submission (DrPLCM) and Blueteq.
- 2.11 Blueteq is a web-based tool that provides assurance to commissioners and providers that the eligibility criteria within clinical commissioning policies and NICE Technical Appraisals (NICE TAs) are adhered to in the treatment of patients.
- 2.12 As [NICE](#) has approved inclisiran for a sub-population of the license, NHS England is seeking assurance that inclisiran is being offered to the cohorts of patients most likely to benefit to support reimbursement.
- 2.13 The use of inclisiran needs to be reported under:
- Commissioned Service Category Code = 21
 - Commissioned Service Category Code Description = NHS ENGLAND - SPECIALISED SERVICES
- 2.14 A Blueteq form for inclisiran, which sets out only the essential data for collection to minimise administrative burden, need to be completed and is available to secondary care providers by logging into their Blueteq account at <https://www.blueteq-secure.co.uk/trust/default.aspx>.
- 2.15 Trusts must ensure that they are purchasing inclisiran at the Contract Price agreed with Novartis, which is set out in the CAP portal. This discounted price will be applied automatically at point of invoice and applies to all indications. Please note the Contract Price for inclisiran is strictly confidential information.

2.16 Information on how to order inclisiran is detailed at 3.11.

Why was a change to secondary care funding implemented?

2.17 Patients within the secondary prevention pathway for cardiovascular disease, including those eligible for inclisiran, are seen in both primary and secondary care settings. Following introduction to the NHS in England, it was identified that more patients than initially anticipated may be initiated on inclisiran in secondary care until primary care administration becomes more established.

2.18 It was determined that tariff payments did not reimburse trusts appropriately for the cost of inclisiran. NHS England has reviewed and updated this position, so that from 01 April 2022 inclisiran was added to the excluded drug list. NHS England applied this arrangement from 01 January 2022 allowing trusts to recharge the cost of inclisiran to NHS England. This change removes any perceived cost barrier to patient access to inclisiran in secondary care.

2.19 Inclisiran remains available to initiate and prescribe in primary care, where most patients with established atherosclerotic cardiovascular disease (ASCVD) are managed. While it is anticipated that the change to the reimbursement of inclisiran in secondary care removes any perceived barriers to initiation and grow experience of use in secondary care, primary care and a population health-based approach remain the preferred route for initiation and patient management on inclisiran, to ensure access for all.

2.20 Systems should support initiation and management of this therapy in the most appropriate setting for the patient, for example, implementing processes to ensure primary care is able to prescribe and administer inclisiran so that when a patient is identified as eligible for treatment a request can be made from secondary care to the patient's GP to initiate treatment.

3. Supply overview

Primary care

- 3.1 Inclisiran is available to order for same day or next delivery from a local AAH branch (<http://www.aah.co.uk/s/our-locations>), you can order inclisiran using AAH Point or your Patient Medication Record (PMR) system using the following codes:

Product Name	EAN Code	PIP Code
Inclisiran (Leqvio®)	7613421044237	4174751

- 3.2 If you need any further support regarding the ordering of inclisiran, please contact AAH Customer Care. You can Live Chat with an agent via AAH Point from 9am-5pm Monday to Friday or call them on 0344 5618899.

Prescribing Options

- 3.3 Community Pharmacy: The prescriber issues an FP10 document, usually via the Electronic Prescription Service (EPS), to the patient to be dispensed via community pharmacy. The patient then returns to the practice (or alternative locally agreed service) for administration. As set out in point 2.4 above, inclisiran is a 'discount is not deducted' so the discount deduction (also known as "clawback") is not applied. Please note via this route a prescription charge for the patient is applicable in line with the current regulations ([The National Health Service \(Charges for Drugs and Appliances\) \(Amendment\) Regulations 2021 \(legislation.gov.uk\)](#)).
- 3.4 General Practice: In addition to the typical approach of issuing an FP10 prescription to the patient to be dispensed via community pharmacy (see Point 3.3), a prescriber can order inclisiran directly from the wholesaler (AAH), administer to the patient and submit to the [NHSBSA](#) via the FP34D / FP34PD submission document for payment purposes. Please note via this route a prescription charge for the patient is not applicable.

- 3.5 Inclisiran, as an injectable treatment, is considered a personally administered (PA) item.
- 3.6 For an HCP to administer a PA item they do not have to be a dispensing practice. Prescribing HCPs can administer PA items in their surgery and claim payment for this treatment which is covered by section 16 of the [General Medical Services Statement of Financial Entitlements](#).
- 3.7 The FP34PD form is the submission document that a non-dispensing GP should use to send all claims for a personally administered item (including inclisiran). The claims will be made via an FP10 form via EPS.
- 3.8 A Dispensing Doctor can either;
- (a) Prescribe via an FP10, dispense and then administer the treatment to the patient. The Dispensing Doctor will then submit to the [NHSBSA](#) via the FP34D submission document for payment purposes. Dispensing fees are set out in the GP contract. Please note via this route a prescription charge for the patient is applicable as per current regulations ([The National Health Service \(Charges for Drugs and Appliances\) \(Amendment\) Regulations 2021 \(legislation.gov.uk\)](#)).
 - (b) Or; order inclisiran directly from the wholesaler (AAH), and administer as a PA item in their surgery and claim payment for this treatment and submit to the [NHSBSA](#) via the FP34PD submission document for payment purposes. This is covered by section 16 of the General Medical Services Statement of Financial Entitlements. Please note via this route a prescription charge is not incurred by the patient.
- 3.9 Please note that VAT is payable on inclisiran when ordered directly from the wholesaler (AAH). Inclisiran, as an injectable, is considered a Personally Administered Item and a VAT allowance is added to payment claims, at the

prevailing VAT rate, in recognition of this incurred cost (as per section 16 of the [General Medical Services Statement of Financial Entitlements](#)).

Secondary care

3.10 Inclisiran is available from Novartis Pharmaceuticals. Details are as follows:

Generic Name / Brand Name	Inclisiran (Leqvio®)
Strength	284mg Inclisiran in 1.5ml Solution
Formulation	Pre-Filled Syringe
Pack Size	1 x PFS (1.5 x 189mg/ml)
Manufacturer's Code	759602
EAN Code	7613421044237
Product Licence Number	EU/1/20/1494/001
VAT	20%
Legal Category	POM
Minimum Order Quantity	N/A
Shelf Life	3 years
Storage conditions	Do not freeze.

3.11 Inclisiran is available to order directly from the Novartis Customer Care team who can be contacted via telephone: 08457 419 442, fax: 08457 419 443 or e-mail: commercial.team@novartis.com.

3.12 Full prescribing information can be found in the Summary of Product Characteristics (SmPC). This, along with the Patient Information Leaflet (PIL) can be found at <http://emc.medicines.org.uk/>.

4. Additional Information

- 4.1 NHS England has agreed to fund inclisiran centrally until July 2024. At this point the agreement will be assessed to establish whether it has met its objectives and an assessment will take place to determine whether the current pricing approach should continue or whether a revised commercial agreement, reflective of the population treated at that time and anticipated for the future, is appropriate.
- 4.2 In line with NICE's standard review timings, a review of the Technology Appraisal (TA) would be expected in 2024 which will ensure there is continued cost effectiveness. Any review of the pricing approach would be in the context of the NICE TA review to ensure that the cost effectiveness of inclisiran remains.
- 4.3 The introduction of inclisiran into the lipid management pathway in primary care is part of a broader programme of work being undertaken at NHS England that supports the use of all NICE approved treatments for lipid management. Further information can be found by visiting [this page](#). Additionally, if you would like to request an introduction from your local Academic Health Science Network (AHSN) lipids lead please use the contact details below.
- 4.4 For any general enquiries about inclisiran or other treatments within the lipid management pathway please use the contact england.lipidsphm@nhs.net.

5. Frequently Asked Questions

This section is to provide the reader answers to frequently asked questions (FAQ) related to the funding and supply of inclisiran (Leqvio®).

If there are any questions that have not been covered within this document or you have a general query, please send an email to: england.lipidsphm@nhs.net.

Question	Response
Funding Overview	
It is stated that inclisiran (Leqvio®) is funded centrally by NHS England. Is there a cost impact to the ICB drugs budget for inclisiran (Leqvio®)?	Yes, the reimbursement price of £55 (£50 from 01 April 2023) per syringe of inclisiran (Leqvio®) will be charged to the local ICB drugs budget.
What is the purchase price for inclisiran (Leqvio®) being dispensed to NHS patients?	In primary care the purchase price for inclisiran (Leqvio®), as charged to the practice, is £45 per syringe.
What is the purchase price for inclisiran (Leqvio®) to private patients?	In primary care the purchase price for inclisiran (Leqvio®) is the NHS List Price and it must be stated when ordering via AAH that this is for a private patient. Note: Stock for private patients must be ordered directly from Novartis Customer care who can be contacted via telephone: 08457 419 442, fax: 08457 419 443 or e-mail: commercial.team@novartis.com
Inclisiran (Leqvio®) is stated at a 'discount is not deducted' in the drug tariff; is this applicable for community pharmacy and general practice?	In a general practice discount deductions (known as "clawback") are applied to reimbursements (irrespective of the actual purchase price) whereas in community pharmacies a number of drugs, including inclisiran, are classified as 'discount is not deducted' (DND) and thus, have no discount deduction ("clawback") applied to the reimbursement the pharmacy receives. The 'discount is not deducted' (DND) is not applicable to general practice and the discount deduction ("clawback") rate will be deducted from the Reimbursement Amount for inclisiran.
What are the fees associated with inclisiran when personally administered?	GP practices will be entitled to the appropriate dispensing fee, as set out in Annex G of the

	<u>Statement of Financial Entitlements Directions 2021</u>
Noting that for general practice inclisiran is reimbursed at £55 (£50 from 01 April 2023) per injection against the £45 Nominal Charge of £45 plus £10 (£5 from 01 April 2023), are there incentives to support its use?	There are not specific incentives to support the use of inclisiran and the focus of incentives is not drug specific but on broader care delivery (e.g. against a care pathway). However, from 01 April 2023 two new broader lipid management indicators (worth 30 points ~ £36m) will be added to the general practice Quality Outcome Framework.
Supply Overview	
Where are the AAH local branches?	AAH local branches refers to the 14 locations across the UK. Details of the local branches can be found at https://www.aah.co.uk/s/our-locations
My local branch has stated they are out of stock, and I have not received notification of a national stock out situation; who do I contact for support?	Any issues with AAH that cannot be resolved with AAH directly should be escalated to Novartis via the following email address: commercial.team@novartis.com
AAH have added a delivery surcharge to my order. What is this?	<p>If a practice purchases only Novartis solus lines i.e. Leqvio and Entresto, they will not be charged a low account surcharge.</p> <p>Note: the AAH low account surcharge threshold for pharmacy is £4,000 for the month and £1,500 for the month for Dispensing Doctors, it is not a charge per delivery (this is accurate at the point of publication but these costs should be confirmed with AAH).</p> <p>Note: if a customer is buying non-solus lines during the month and their total spend does not meet the threshold then they will be charged a low account surcharge.</p>
Is there a flag or a 'marker' on my account that needs to be removed before I can order inclisiran at the nominal charge of £45?	<p>AAH review all GP and Pharmacies when the first order is placed to ensure they have access to the nominal charge for Inclisiran.</p> <p>This allows AAH to provide the relevant information regarding the price differential between NHS and private scripts.</p> <p>There is no cost or time delay it is just a due diligence process to make sure that drugs are being delivered to the eligible customers at the appropriate price.</p>

<p>Can a non-dispensing doctor order inclisiran (Leqvio®)? How do I reclaim for reimbursement costs?</p>	<p>Yes, any general practice can order inclisiran directly from the wholesaler (AAH), administer to the patient and write an FP10 to submit to the NHSBSA for payment purposes. Please note via this route a prescription charge for the patient is not applicable.</p>
<p>I have short dated or out of date stock. Who do I contact for a replacement or credit note?</p>	<p>Please contact Novartis via the following email address: commercial.team@novartis.com</p>
<p>Reimbursement Overview</p>	
<p>In support of at scale delivery can GP Federations provide inclisiran (Leqvio®) claim via FP34d route via section VIIIIC of the drug tariff?</p>	<p>GP Federations are unable to claim for inclisiran via FP34d route via section VIIIIC of the drug tariff.</p> <ul style="list-style-type: none"> • The wording on the FP34D/PD submission documents makes it clear that the submission is to be made by a GP practice. • The SFE covers payments and submissions where the mention of 'contractors' refers to GPs and practices. <p>Both points indicate that claims for payment should be made by an individual GP/practice and not by a GP Federation. Therefore, the ordering arrangement that apply to individual GP practice apply (i.e. the Federation has no status above and beyond that of the individual GP practices and ordering would need to be through these).</p> <p>The alternative is that the GP Federation is a recognised healthcare provider operating through the prevailing NHS Standard Contract and should be ordering in the same way as any other designated provider of NHS services.</p>

6. Glossary

Term	Description
Nominal charge	This is the amount that primary care providers and community pharmacy pay for Inclisiran and can access from the wholesaler (AAH) at £45. This amount is below the Contract Price of inclisiran and is in place to make sure inclisiran is easily accessible to primary care and keep ICB budget impact low.
Reimbursement amount	This is the amount reimbursed, £55 (£50 from 01 April 2023), to primary care providers and community pharmacy contractors in England and is cited in part VIIC of the drug tariff.
Discount deduction (also known as 'clawback')	<p>A system of deduction from reimbursements paid to general practice is automatically made by NHS prescription pricing authorities (NHS BSA) to account for assumed profits made on drugs purchases.</p> <p>Further information regarding the discount application can be found here.</p>
Discount is not deducted (DND)	A number of drugs are classified as 'discount is not deducted' (DND) in the Drug Tariff and thus, for <i>community pharmacy</i> have no discount deducted ("clawback") applied to the reimbursement the pharmacy receives.
List price	This is the price listed in the Dictionary of Medicines & Devices (DM&D) by the Department of Health and Social Care. This price is publicly accessible.
Contract price	This is actual price of inclisiran that Novartis charges NHS England for the purchase, supply and use of inclisiran at any NHS care provider, irrespective of primary or secondary care. This price is confidential.

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This publication can be made available in a number of alternative formats on request.

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