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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 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, including an important update on the funding for inclisiran in secondary care from 01 January 2022.
- 1.2 This document is relevant for any healthcare professional involved in the prescribing, funding and supply of inclisiran.

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 the local uptake of inclisiran. To enable general practice and community pharmacy to be able to purchase inclisiran directly from the national wholesaler (AAH) for the medicine, a 'Nominal Charge', has been agreed at which they will be able to purchase the medicine.
- 2.2 Inclisiran is available from the wholesaler (AAH) at £45 (Nominal Charge), which is payable 30 days from the end of that month. Inclisiran is listed in the Drug Tariff as a 'zero discount' item (no claw-back applicable).
- 2.3 Inclisiran is available in general practice as a personally administered item reimbursed via an FP34D form or on an FP10 prescription, and is listed in the Drug Tariff (Part VIII C) at a Reimbursed Amount of £55 per injection.
- 2.4 The cost to the CCG and primary care prescribing budget will be the Reimbursement Amount set out above.
- 2.5 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

- 2.6 Inclisiran will be added to the PbR excluded drug list from April 2022 and will be reimbursed centrally by NHS England. NHS England will shadow this arrangement from 1 January 2022. Prior to this change (September – December 2021) the Trust was charged the confidential contract price via the CAP portal when ordering stock of inclisiran and did not receive reimbursement.
- 2.7 Inclisiran used by trusts will, as of 1 January 2022, be funded via the interim High Cost Drug cost and volume arrangements for Specialised High Cost Drugs as set out in the 'Guidance on finance and contracting arrangements for H2 2021/22' published on 30 September 2021:
<https://www.england.nhs.uk/wp-content/uploads/2021/09/C1406-guidance-on-finance-and-contracting-arrangements-h2-21-22.pdf>
- 2.8 Inclisiran will be reimbursed under the cost and volume process. In line with the terms and conditions included in 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, ie, complete and accurate information in the provider's drugs patient level contract monitoring data submission (DrPLCM) and Blueteq.
- 2.9 The use of inclisiran needs to be reported under:
- Commissioned Service Category Code = 21
 - Commissioned Service Category Code Description = NHS ENGLAND - SPECIALISED SERVICES
- 2.10 A Blueteq form for inclisiran is now available for use on provider systems.
- 2.11 Trusts must ensure that they are purchasing inclisiran at the Contract Price agreed with Novartis. 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.

Why has a change to secondary care funding been implemented?

- 2.12 Patients within the secondary prevention pathway for cardiovascular disease, including those eligible for inclisiran, are seen in both primary and secondary care clinics. Following introduction to the NHS in England, it has been identified that more patients than initially anticipated may be initiated on inclisiran in secondary care until primary care administration becomes more established.
- 2.13 As such, it was determined that tariff payments did not reimburse trusts appropriately for the cost of inclisiran and so NHS England has reviewed and updated this position, so that from 1 April 2022 inclisiran will be added to the excluded drug list but NHS England has agreed to apply these arrangements in shadow form from 1 January 2022, ie trusts can recharge the cost of inclisiran to NHS England. This change should remove any perceived cost barrier to patient access to inclisiran in secondary care.
- 2.14 Inclisiran remains available to initiate and prescribe in primary care, where most patients with established ASCVD are managed. While we anticipate that the change to the reimbursement of inclisiran in secondary care should remove 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.
- 2.15 As such, 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 is made from secondary care to the patient's GP to initiate treatment.

Why is a Blueteq form required in secondary care?

- 2.16 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.

2.17 As NICE has approved inclisiran for a sub-population of the license, NHS England and NHS Improvement is seeking assurance that inclisiran is being offered to the cohorts of patients most likely to benefit to support reimbursement. The AAC has developed a Blueteq form, circulated alongside this overview document, which sets out only the essential data for collection to minimise administrative burden.

3. Supply overview

Primary care

3.1 Inclisiran, from Novartis, funded by NHS England, is available to all pharmacies and GPs for prescribed patients. Available to order for same day or next delivery from your local branch, you can order inclisiran (Leqvio®) using AAH Point or your 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 inclisiran (Leqvio®), please contact AAH Customer Care. You can Live Chat with via AAH Point from 9am-5pm Monday to Friday or call them on 0344 5618899.

Non-dispensing doctors

3.3 In addition to the typical approach of issuing an FP10 document to the patient to be dispensed via community pharmacy, a Prescribing GP can order inclisiran directly from the wholesaler, 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.

3.4 Inclisiran, as an injectable treatment, is considered a personally administered (PA) item; further detailed in section 16 of the Statement of Financial Entitlement (SFE).

3.5 For a GP to administer a PA item they do not have to be a dispensing practice. Prescribing GPs can administer PA items in their surgery and claim payment for this treatment which is covered by section 16 of the SFE.

Submitting the claim

- 3.6 Declaration forms, known as ‘submission documents’, are required when making monthly claims.
- 3.7 The form used differs depending on the type of dispensing contractor (eg appliance contractor or dispensing doctor) and item dispensed (eg medical appliance or high-volume personally administered vaccine)
- 3.8 For example, non-dispensing doctors use: FP34PD submission document (Peach) when claiming for a general personally administered item with supporting FP10 documents. Please note, the FP34PD appendix form used when claiming for a high-volume personally administered vaccine item is not applicable for inclisiran.

Reimbursement: PA allowance and dispensing fee

	Calculation Formula	Inclisiran Example @ a discount price of £45 per pre-filled syringe	Total
Basic Price (BP) = £55	(BP-discount)	£55-£45	£ 10.00
Clawback rate (CBR)	BP x CBR	£55 * 0%	£ -
VAT Allowance (VAT)	(BP-CBR) x 20%	£55 * 20%	£ 11.00
Dispensing Fee (DF) ¹	DF	£2.21	£ 2.21
PA Allowance	(BP-CBR) + VAT +DF	£55 + £11 +£2.21	£ 68.21
Income			£ 23.21

¹ Assumed dispensing fee of £2.21

Further information on personally administered (PA) items:

- The NHS pays a PA allowance as reimbursement for sourcing and administering PA items
- PA allowance is calculated by the NHS and can differ between practices
- This PA allowance is calculated based on the NHS ‘Nominal Charge’ including VAT, not the discounted price you pay to the wholesaler
- Dispensing fees vary depending on the number of items submitted for reimbursement per an individual GP
- Dispensing fees decrease when >457 items are allocated to an individual doctor

Dispensing doctors

- 3.9 A prescribing GP can issue an FP10 and the patient takes this to be dispensed via the in-practice pharmacy. The GP then administers the

treatment to the patient. The pharmacy will submit the FP10 for payment and reimbursement purposes following the same process set out above for non-dispensing doctors where the doctor administers a PA item. Please note via this route a prescription charge for the patient is not applicable.

Community pharmacy

3.10 A prescribing GP (typical non-dispensing) can issue an FP10 to a patient; this can then be taken to a community pharmacy, designated by the patient, to be dispensed. The patient takes the treatment back to the GP for administration. The community pharmacy will submit the FP10 for payment and reimbursement purposes. The PA fee is not payable to community pharmacy. Please note via this route a prescription charge is applicable for the patient.

Secondary care

3.11 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.

3.12 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.

3.13 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 and NHS Improvement has agreed to fund inclisiran centrally until the initial agreement review date (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 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 by the Accelerated Access Collaborative at NHS England, and Academic Health Science Network. Further information can be found by visiting [this page](#). Additionally, if you would like to request an introduction from your local AHSN lipids lead please complete [this form](#).
- 4.4 For any general enquiries about the AAC/AHSN Lipid Management Programme of work, inclisiran or other treatments within the lipid management pathway please use the contact details below.

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