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# Funding and supply of inclisiran (Leqvio®)

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## 1. Introduction

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 NICE set out in TA733 on 6 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 or supply of inclisiran. We have updated it to include additional information on funding and new frequently asked questions and glossary entries.

## 2. Funding overview

### Primary care

2.1 NHS England is funding inclisiran centrally from a national NHS budget so that local finances are not a barrier to access. General practice and community pharmacy can purchase inclisiran directly from the national wholesaler (AAH) at an agreed 'nominal charge' that helps 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 \(https://www.gov.uk/guidance/health-professionals-pharmaceutical-products-and-vat-notice-70157\)](#)). 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 it is listed in the Drug Tariff (Part VIIIC) at a reimbursed amount from 1 April 2025 of £60 per injection (the £45 nominal charge identified at paragraph 2.2 plus £15; previously £45 plus £5).

2.4 Inclisiran is listed in the Drug Tariff as a 'discount is not deducted' item, meaning for pharmacy contractors no discount deduction (also known as 'clawback') is applied to the reimbursed amount (£60 from 1st April 2025; previously £50) listed in the Drug Tariff.

2.5 For general practice, inclisiran will be reimbursed at the reimbursed amount set out in the Drug Tariff. From 1 October 2024, recognising that the treatments in Part VIIIC(ii) of the Drug Tariff are subject to national commercial deals that fix the nominal price to be paid for the treatment, for general practice discount deduction ('clawback') will not be applied to the treatments in this section of the Drug Tariff (that is, they will effectively be treated as 'discount not deducted'). Please see [The General Medical Services Statement of Financial Entitlements \(Amendment\) \(No. 2\) Directions 2024 \(https://assets.publishing.service.gov.uk/media/66f6ba8ea31f45a9c765edf3/general-medical-services-statement-financial-entitlements-amendment-2-directions-2024.pdf\)](#).

2.6 The cost to the ICB and primary care prescribing budget will be the reimbursement amount of £60 set out in paragraph 2.3.

2.7 As the nominal charge is set below the contract price agreed with Novartis, a separate payment will be made to Novartis from a central NHS budget for the difference between the two. This will not impact on local budget.

## Secondary care

2.8 Inclisiran is on the Payment by Results (PbR) excluded drug list since 1 April 2022 and is reimbursed centrally by NHS England.

2.9 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; that is, complete and accurate information in the provider's drugs patient-level contract monitoring data submission (DrPLCM). From 1 April 2025, a prior approval form (for example, Blueteq) is no longer required for initiation or subsequent treatments. However, submission via the Drugs Patient Level Contract Monitoring (DrPLCM) remains in place.

2.10 As the [National Institute for Health and Care Excellence \(NICE\)](https://www.nice.org.uk/guidance/ta733) has approved inclisiran for a subpopulation of the licence (<https://www.nice.org.uk/guidance/ta733>), NHS England reserves the right to seek assurance that inclisiran is being offered to the cohorts of patients most likely to benefit, to support reimbursement.

2.11 The use of inclisiran needs to be reported under:

- Commissioned service category code = 21
- Commissioned service category code description = NHS ENGLAND – SPECIALISED SERVICES

2.12 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 for all indications at point of invoice. Please note the contract price for inclisiran is strictly confidential information.

2.13 Information on how to order inclisiran is detailed at paragraph 3.11.

2.14 NHS England remains committed to supporting clinical trials, including supporting patients coming off trials to continue to access treatments. It is our expectation that provision should be made when research trials are initiated for patients to continue to access treatment. However, we recognise that at the point some trials started, inclisiran was not yet licensed or available on the NHS. While the costs of inclisiran are met nationally, there still needs to be local ownership and decision-making. As such, trusts should liaise with their ICB to confirm the appropriateness of patients continuing with treatment (that is, to maintain their reduced lipid levels) and its support for patients coming off trial to continue to access the treatment. If the ICB is supportive, then costs of the treatment would continue to be met nationally as per the arrangement detailed in paragraphs 2.8 to 2.12.

## 3. Supply overview

### Primary care

3.1 Inclisiran is available to order for same day or next delivery from a local AAH branch. You can order it using AAH Point or your Patient Medication Record (PMR) system under the following codes:

Product name	EAN code	PIP code
Inclisiran (Leqvio®)	07613421107178	4174751

3.2 If you need any further support to order inclisiran, please contact AAH Customer Care. You can live chat with an agent via AAH Point from 9am to 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 paragraph 2.4, inclisiran is a 'discount not deducted' item so the discount deduction ('clawback') is not applied. Please note that via this route a prescription charge applies to the patient in line with the current regulations ([The National Health Service \(Charges for Drugs and Appliances\) \(Amendment\) Regulations 2021](https://www.legislation.gov.uk/uksi/2021/178/made) (<https://www.legislation.gov.uk/uksi/2021/178/made>)).

**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 paragraph 3.3), a prescriber can order inclisiran directly from the wholesaler (AAH), administer it to the patient and submit the FP34D / FP34PD submission document to the [NHS Business Services Authority \(NHSBSA\)](https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/submitting-prescriptions/sending-your-claim) (<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/submitting-prescriptions/sending-your-claim>) for payment purposes. Please note that via this route a prescription charge does not apply to the patient.

3.5 As an injectable treatment, inclisiran is considered a personally administered (PA) item. For a healthcare professional (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 Directions](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975395/GMS_SFE_2021) ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/975395/GMS\\_SFE\\_2021](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975395/GMS_SFE_2021)).

3.6 A non-dispensing GP practice should use the FP34PD submission document to send all claims for personally administered items (including inclisiran). It is important to note this is not a reference to the FP34PD high volume appendix form (which is used for vaccines). Inclisiran administration should not be entered on that; it should be counted in the FP34PD submission document. If inclisiran is submitted on the FP34PD high volume appendix form, NHSBSA will disallow the claims. If incorrect claims are made, GP practices can resubmit following the correct process outlined in paragraph 3.7.

3.7 As well as including inclisiran in the FP34PD submission document, non-dispensing GP practices submit an individual FP10 for each inclisiran injection as this will trigger payment for the dispensing fee and reimbursement of the drug cost. Doing so is important as practices may not receive income they are due if they do not submit the FP10. The FP10 forms, FP34PD submission document and prescribing doctor details and totals form should all be returned to receive the income due.

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 (<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/submitting-prescriptions/sending-your-claim>) via the FP34D submission document for payment purposes (the FP34D annex should not be used – see paragraph 3.6). Dispensing fees are set out in the GP contract. Please note that via this route a prescription charge applies to the patient as per current regulations ([The National Health Service \(Charges for Drugs and Appliances\) \(Amendment\) Regulations 2021](https://www.legislation.gov.uk/uksi/2021/178/made) (<https://www.legislation.gov.uk/uksi/2021/178/made>)).

or

- b. order inclisiran directly from the wholesaler (AAH), administer it as a PA item in their surgery and claim payment for this treatment. The dispensing doctor will then submit to the NHSBSA (<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/submitting-prescriptions/sending-your-claim>) via the FP34PD submission document, with the corresponding FP10s, for payment purposes (the FP34D annex should not be used – see paragraph 3.6). This is covered by section 16 of the General Medical Services Statement of Financial Entitlements Directions. Please note that via this route the patient does not incur a prescription charge.

3.9 Please note that VAT is payable on inclisiran when ordered directly from the wholesaler (AAH). Inclisiran, as an injectable, is considered a PA 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 Directions](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975395/GMS_SFE_2021) ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/975395/GMS\\_SFE\\_2021](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975395/GMS_SFE_2021))).

3.10 Dispensing practices should seek their own advice on the handling of VAT.

## Secondary care

3.11 Inclisiran is available from Novartis. Details are as follows:

<b>Generic name / brand name</b>	Inclisiran (Leqvio®)
<b>Strength</b>	284 mg Inclisiran in 1.5 mL solution
<b>Formulation</b>	Pre-filled syringe
<b>Pack size</b>	1 x PFS (1.5 x 189 mg/mL)
<b>EAN code</b>	07613421107178

<b>Product licence number</b>	EU/1/20/1494/001
<b>VAT</b>	20%
<b>Legal category</b>	POM
<b>Minimum order quantity</b>	N/A
<b>Shelf life</b>	3 years
<b>Storage conditions</b>	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, or email: [novartis.customercare@novartis.com](mailto:novartis.customercare@novartis.com) (<mailto:novartis.customercare@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/> (<http://emc.medicines.org.uk/>).

#### 4. Additional information

4.1 NHS England has agreed to continue to fund inclisiran centrally for all patients initiated on treatment prior to 31 December 2027. At this point, the agreement will be assessed to determine whether the current approach should continue or a revised commercial agreement is appropriate. Any revisions to the commercial agreement from 1 January 2028 will apply for new patients only. Arrangements for patients already on treatment prior to 1 January 2028 will remain in place.

4.2 Inclisiran should be used as part of a lipid management pathway. Information on lipid management guidance and pathway is given in:

- a. [NICE \[NG238\] Cardiovascular disease: risk assessment and reduction, including lipid modification \(December 2023\)](https://www.nice.org.uk/guidance/ng238) (<https://www.nice.org.uk/guidance/ng238>)
- b. [Summary of national guidance for lipid management and lipid management pathways](https://www.england.nhs.uk/aac/publication/summary-of-national-guidance-for-lipid-management/) (<https://www.england.nhs.uk/aac/publication/summary-of-national-guidance-for-lipid-management/>).

#### 5. Frequently asked questions

This section provides answers to frequently asked questions about the funding and supply of inclisiran (Leqvio®).

If you have any questions on pricing or commercial agreement that have not been answered here, please contact [england.commercialmedicines@nhs.net](mailto:england.commercialmedicines@nhs.net) (<mailto:england.commercialmedicines@nhs.net>).

#### Funding overview

##### 1. It is stated that inclisiran (Leqvio®) is funded centrally by NHS England. Is there a cost impact on the ICB drugs budget for inclisiran (Leqvio®)?

Yes, the reimbursement price of £60 from 1 April 2025 per syringe of inclisiran (Leqvio®) will be charged to the local ICB drugs budget.

##### 2. 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.

##### 3. 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 when ordering inclisiran via AAH it must be stated that this is for a private patient.

Note: Stock for private patients must be ordered directly from the Novartis Customer Care team who can be contacted via telephone: 08457 419 442, or email: [novartis.customercare@novartis.com](mailto:novartis.customercare@novartis.com) (<mailto:novartis.customercare@novartis.com>).

#### **4. What is the fee for inclisiran when it is personally administered?**

GP practices will be entitled to the appropriate dispensing fee, as set out in [Annex G of the Statement of Financial Entitlements Directions 2021](#) ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/975395/GMS\\_SFE\\_2021](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975395/GMS_SFE_2021)).

#### **5. Noting that for general practice inclisiran is reimbursed at £60 per injection from 1 April 2025, against the £45 nominal charge, are there incentives to support its use?**

There are no specific incentives to support the use of inclisiran and the focus remains on a clinical pathway, with patients where appropriate first supported with high intensity statins.

### **Supply overview**

#### **6. Where are the AAH local branches?**

AAH local branches are at [locations across the UK](#) (<https://www.aah.co.uk/s/our-locations>).

#### **7. My local branch has stated it is 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 email: [novartis.customercare@novartis.com](mailto:novartis.customercare@novartis.com) (<mailto:novartis.customercare@novartis.com>).

#### **8. AAH has added a delivery surcharge to my order. What is this?**

If a practice purchases only Novartis solus lines – that is, Leqvio and Entresto, they will not be charged a low account surcharge.

Note: the AAH low account surcharge is not a charge per delivery. The surcharge threshold for pharmacy is £4,000 for the month and £1,500 for the month for dispensing doctors (this information is accurate at the point of publication but these costs should be confirmed with AAH).

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.

#### **9. 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?**

AAH reviews all GP practices and pharmacies when they first place an order to ensure they have access to the nominal charge for inclisiran.

This allows AAH to provide the relevant information regarding the price differential between NHS and private scripts.

This review carries 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.

#### **10. Can a non-dispensing doctor order inclisiran (Leqvio®)? How do I reclaim for reimbursement costs?**

Yes, any general practice can order inclisiran directly from the wholesaler (AAH), administer it to the patient and write an FP10 to submit to the NHSBSA for payment purposes. Please note that via this route a prescription charge does not apply to the patient.

#### **11. I have short dated or out of date stock. Who do I contact for a replacement or credit note?**

Please contact Novartis via email: [novartis.customercare@novartis.com](mailto:novartis.customercare@novartis.com) (<mailto:novartis.customercare@novartis.com>).

## Glossary

**Nominal charge:** This is the amount that primary care providers and community pharmacy pay for inclisiran. It can be accessed from the wholesaler (AAH) at £45, which is below the contract price for inclisiran to make sure inclisiran is easily accessible to primary care and to keep impact on ICB budget low.

**Reimbursement amount:** This is the amount reimbursed, £60 from 1 April 2025, to primary care providers and community pharmacy contractors in England. It is cited the Drug Tariff (Part VIIIC).

**Discount deduction (also known as ‘clawback’):** NHS prescription pricing authorities (NHSBSA) automatically apply a system of deduction from reimbursements paid to general practice, to account for assumed profits made on drug purchases.

**Discount is not deducted (DND):** Some drugs are classified as ‘discount is not deducted’ (DND) in the Drug Tariff. Discount is not deducted (‘clawback’) from the reimbursement community pharmacies receive for these.

From 1 October 2024, recognising that the treatments in Part VIIIC(ii) of the Drug Tariff are subject to national commercial deals that fix the nominal price to be paid for the treatment, for general practice discount deduction (‘clawback’) will not be applied to the treatments in this section of the Drug Tariff (that is, they will effectively be treated as ‘discount not deducted’). Please see [The General Medical Services Statement of Financial Entitlements \(Amendment\) \(No. 2\) Directions 2024](https://assets.publishing.service.gov.uk/media/66f6ba8ea31f45a9c765edf3/general-medical-services-statement-financial-entitlements-amendment-2-directions-2024.pdf) (<https://assets.publishing.service.gov.uk/media/66f6ba8ea31f45a9c765edf3/general-medical-services-statement-financial-entitlements-amendment-2-directions-2024.pdf>).

**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 the **actual** price 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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