

INCLISIRAN: REQUESTS FOR GP PRESCRIPTION AND ADMINISTRATION

Sheffield
LMC



GUIDANCE FOR SHEFFIELD GPs January 2024

It has been brought to our attention that GPs are being asked to prescribe and administer Inclisiran.

We are concerned about a black triangle drug being pushed into General Practice prior to any outcome data or safety evidence from hospital administration being available. This is reflected by both the [Royal College of General Practitioners \(RCGP\)](#) and the [British Medical Association \(BMA\)](#).

As ever, the individual clinician (prescriber) needs to assure themselves that they have all the relevant information before prescribing any medication, and needs to take into account national and local guidance. Where guidance states that medication(s) can be prescribed in General Practice, it is important to note that it does not mean that it should be prescribed in General Practice.

We have been in discussions about the push for GPs to prescribe Inclisiran, and have raised the following concerns with the Lipid Clinic at Sheffield Teaching Hospitals NHS Foundation Trust (STHFT):

1. GPs are not commissioned to deliver Inclisiran, and it is not part of GPs' core General Medical Services (GMS) contract.
2. There is no Locally Commissioned Service (LCS) offered to allow GPs to do this.
3. The core contract is a national one and cannot be overridden by local suggestions from Sheffield Area Prescribing Group (APG) or the South Yorkshire Integrated Medicines Optimisation Committee (IMOC). We have made it very clear at both of these fora that GPs are not commissioned to deliver Inclisiran.
4. There is no robust clinical evidence available for the outcomes associated with Inclisiran. The proposed study to establish this has had a massively reduced recruitment plan, and will not be available for some time. Long term efficacy data is due to be published in 2026 (Orion 4). Whilst there is evidence to suggest that low-density lipoprotein (LDL) cholesterol reduction reduces cardiovascular disease (CVD) events, this cannot be translated to mean that Inclisiran will decrease CVD events. The study to evaluate delivery in General Practice has also been delayed, despite it being recommended by the National Institute for Health and Care Excellence (NICE) that this should happen.
5. NICE guidelines are exactly that and are non-contractual. They should also be viewed in light of GPs' ability to engage patients in shared decision making, so they can make reasoned choices. With no outcome data these conversations cannot take place.
6. There have been [suggestions that there has been undue political pressure](#) put on NICE and Integrated Care Boards (ICBs) to market Inclisiran.
7. The whole NHS has capacity issues, including General Practice, and decisions need to be made on who is commissioned and best placed to deliver this drug safely.