National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of verteporfin 15mg powder for solution for injection

Date of issue:	28-Sep-23	Reference no:	NatPSA/2023/012/DHSC

This alert is for action by: Acute Trusts providing verteporfin therapy for Central Serous Retinopathy

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in ophthalmology, pharmacy procurement and those providing specialist eye treatment.

Explanation of identified safety issue:

Verteporfin is indicated for the treatment of adults with exudative (wet) age-related macular degeneration (AMD) with predominantly classic subfoveal choroidal neovascularisation (CNV) or adults with subfoveal choroidal neovascularisation secondary to pathological myopia. Verteporfin is also used in the treatment of ocular cancer in specialist centres.

Verteporfin is used off-label for the management of central serous retinopathy with photodynamic therapy.

Verteporfin has been in short supply globally since late 2020 due to capacity constraints at the manufacturing site. The issue is not expected to resolve until the middle of 2024.

Since 2021, verteporfin supply has been restricted for use in ocular cancer centres in the UK.

Currently there is a limited quantity of stock available over and above what is required for the treatment of ocular cancer. This excess stock will be made available for treatment of Central Serous Retinopathy (CSR). However, an evaluation of waiting lists in the UK has highlighted that there is insufficient to treat all chronic CSR patients currently on waiting lists. The Royal College of Ophthalmologists has therefore developed a list of prioritisation factors which should be used to evaluate chronic CSR patients currently on waiting lists to determine who are most at need of treatment.

Trusts have been allocated this additional stock based on historic usage prior to the current ongoing supply issue. Trusts who can order stock will be informed of how to obtain supplies by their Regional Pharmacy Procurement Specialist and orders can be placed from 2 October 2023.

Actions required

Actions to be completed by 20/10/2023

1. Ophthalmologists should assess their waiting list of patients with chronic Central Serous Retinopathy who require treatment with verteporfin (off-label use).
2. Ophthalmology teams should prioritise patients according to the clinical guidance produced by the Royal College of Ophthalmology.[NOTE A]
3. Ophthalmology teams should work with pharmacy teams to understand the number of verteporfin vials they have been allocated and apply the ‘half-dose protocol’ (off-label) as per Royal College of Ophthalmology guidance to understand the number of patients who can receive treatment.
4. Pharmacy teams should discuss with their Regional Pharmacy Procurement Specialists (RPPS) if the number of vials allocated is more or less than required. This will allow the RPPS to reallocate stock or escalate the request for further stock, where available, accordingly.
5. Specialists who prescribe verteporfin must continue to review patients and assess whether therapy with verteporfin is required and consider utilising unlicensed imports if they are available.[NOTE B]

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Note A: Clinical guidance

The Royal College of Ophthalmologists have developed a list of prioritisation factors which should be considered when evaluating waiting lists of chronic CSR patients to prioritise those who are most in need of treatment with Photodynamic Therapy (PDT):

Clinical Prioritisation Factors for ½ dose PDT laser.

- CSR in patients with monocular vision
- Patients with bilateral CSR
- Patients with caring responsibilities
- Duration of CSR: patients should have been diagnosed with CSR for more than 4 months and showing no improvement
- Location of sub-retinal fluid: sub-retinal fluid should extend beneath the fovea
- Corrected visual acuity should be worse than or equal to 6/12

Exclusion criteria

- Permanent macular damage for which treatment will not improve vision

Further information on this and the 'Half-Dose' protocol can be found here: https://www.rcophth.ac.uk/wp-content/uploads/2023/09/Clinical-Prioritisation-Guidance-for-Limited-Stock-of-Verteporfin-Visudyne-for-Photodynamic-Therapy-PDT-for-Central-Serous-Chorioretinopathy-CSR.pdf

Note B: Unlicensed product availability

Importers have sourced unlicensed supplies of verteporfin 15mg powder for solution for injection however availability is intermittent and not all suppliers will have stocks at any one time. The Medicine Supply Tool can be accessed to see up to date information on availability of unlicensed imports.

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert:

- Medicine Shortage Response Group,
- Specialist Pharmacy Service Medicines Advice,
- Royal College of Ophthalmologists,
- NHS England National Clinical Director for Eye Care,
- NHS England National Patient Safety Team
- Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 and CHT/2023/002 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.