National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Orencia® ClickJect™ (abatacept) 125mg/1ml solution for injection pre-filled pens

Date of issue:	23-May-24		NatPSA/2024/006/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing, and administering Orencia® ClickJect™ (abatacept) 125mg/1ml solution for injection pre-filled pens

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 rheumatology, dermatology, NHS trust homecare leads, homecare providers and pharmacy services in all sectors.

Explanation of identified safety issue:

Orencia® Clickject™ (abatacept) 125mg/1ml solution for injection pre-filled pens will be out of stock from mid-June 2024 due to a manufacturing issue resulting in delays in production.

From late August, Bristol-Myers Squibb will start to build their stockholding to ensure continuity of supply moving forward. Affected patients should only be switched back to pre-filled pens once supply resilience is confirmed.

Homecare providers (Lloyds Pharmacy Clinical Homecare (LPCH), HealthNet and Polar Speed) have sufficient stock to supply existing patients until week ending 23 June 2024.

Orencia® 125mg/1ml solution for injection pre-filled syringes (PFS) remain available, however, can only support 15% of patients switching to them (see Additional information).

Orencia® 50mg and 87.5mg solution for injection PFS are not currently marketed.

Orencia® 250mg powder for concentrate for solution for infusion vials remain available and can support a full increase in demand.

Not all homecare providers have the capacity to support the administration of Orencia® intravenous infusion at home (see Additional information).

Limited quantities of unlicensed imports of Orencia® pre-filled pens and syringes can be sourced. Lead times vary. Information relating to imports is available on the SPS Medicines Supply Tool which also details any changes to resupply dates and updates to this communication.

Actions required

Actions to be completed as soon as possible and not later than 6 June 2024.

Actions for clinicians, NHS trust homecare leads and homecare providers until supply issues have resolved.

All affected providers MUST:

1. Not start new patients on any Orencia® (abatacept) products.
2. Work with their homecare provider(s) to identify which patients will switch to Orencia® 125mg/1ml PFS, prioritising paediatric patients and those being treated for severe treatment-resistant morphoea.
3. Remaining patients should be reviewed and prescribed Orencia® 250mg powder for concentrate for solution for infusion, if appropriate. Trusts should then:
   a. Work with their homecare provider(s) to understand their capacity for support (see Additional information); and
   b. Organise appointments for patients to receive the infusion in a hospital setting where necessary.
4. Where the above options are not considered appropriate, review patients on a case-by-case basis to consider other treatment options.

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:

The switch to an alternative abatacept presentation is complex, and the management is partially influenced by the homecare provider with whom trusts contract. All patients should be counselled on the change in formulation and frequency of administration, where relevant.

1. Switching to Orencia® 125mg/1ml solution for injection PFS:
All Orencia® homecare providers can support a switch from Orencia® 125mg/1ml pre-filled pens to Orencia® 125mg/1ml PFS without any operational burden to NHS trusts. The homecare providers will work with Bristol-Myers Squibb to provide nurse-led training for specific patients who require any additional support.

Patients will be changed back by the homecare provider to pre-filled pens from late August 2024 onwards.

2. Switching to Orencia® 250mg powder for concentrate for solution for infusion vials:
LPCH have capacity to support the administration of Orencia® IV infusion for most patients and trusts using LPCH should work closely with the company to understand which patients/regions can be supported.

HealthNet cannot support the administration of Orencia® IV infusion in a patient's home. Infusions will need to be administered in a hospital setting wherever possible. Where the hospital setting is not an option, work with HealthNet to understand their capacity for supporting in urgent cases only. Where this is not possible, trusts may contact LPCH to understand their capacity to support additional patients during this time.

Polar Speed can support the administration of Orencia® IV infusion for all patients. Trusts using Polar Speed should work closely with the company to understand how patients/regions can be supported.

Patients can be changed back to Orencia® 125mg/1ml pre-filled pens in a stepwise approach from late August. Patients switched to Orencia® IV infusion should be prioritised for switching back to pre-filled pens.

Clinical information
Orencia® Clickject™ 125mg/1ml pre-filled pens and PFS are licensed for the treatment of rheumatoid arthritis and psoriatic arthritis in adults. Both presentations are administered as weekly subcutaneous injections. A dose of 125 mg is given regardless of weight to adults being treated for these indications.

Orencia® 125mg/1ml PFS are licensed for treatment of polyarticular juvenile idiopathic arthritis using weight based weekly dosing.

Orencia® 250 mg vials are licensed for the treatment of all three of these indications. It is administered as a 30-minute intravenous infusion at the doses specified in the SmPC. Following the initial administration, it is given 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

Orencia® is recommended as a treatment option through routine NHSE commissioning for patients with severe, treatment resistant morphoea (localised scleroderma).[3]

When switching patients stabilised on SC injections to IV infusion, treatment should start on the day the SC dose is due as far as possible, in line with dosing in the SmPC, and repeated 4-weekly.

References:

1. SmPC: Orencia®
2. BNF: abatacept
3. Clinical Commissioning Policy Statement: Abatacept for treatment of severe treatment-resistant morphoea

Stakeholder engagement:
The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS SPS MA, MSRG, NHSE, NCD for Musculoskeletal, Dermatology CRG, representative and national patient safety team, Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and straightforward 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 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.