

15 May 2024

RE: ORENCIA STOCK HYPERCARE PLAN (OSHP) FOLLOW UP COMMUNICATION SERIOUS SCARCITY SUBSTITUTION INSTRUMENT (SSSI)

Dear Pharmacist,

Due to a current shortage of Orencia (abatacept) 125mg/mL prefilled syringe and ClickJect prefilled autoinjector, usage must be significantly reduced and supply tightly constrained to conserve stock for patients with no or limited alternatives. This means most patients will need to switch to other medicines. Given this situation, the Australian Rheumatology Association (ARA) have recommended that this stock be conserved for patients who meet certain eligibility criteria.

Bristol Myers Squibb (BMS) has developed a process to facilitate ordering for patients who meet the ARA's criteria called the **Orencia Stock Hypercare Plan (OSHP)** which was made effective from 22nd April 2024. To support patients on Orencia Subcutaneous formulations during this period, the TGA has put in place the **Serious Scarcity Substitution Instrument (SSSI)**. This SSSI declares Orencia (abatacept) pre-filled syringe and the Orencia (abatacept) 125/mL subcutaneous autoinjector (ClickJect) as scarce and substitutable medicines, making the medicines effectively interchangeable at the pharmacy level. For more details, please refer to TGA website: https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-2024-shortage-orencia-abatacept-medicines

As a result, we have updated the process for ordering via the OSHP to include SSSI.

For the duration of the OSHP:

- 1) <u>Treating physicians (being a Rheumatologist/Clinical Immunologist) will need to:</u>
 - Determine if patients are eligible to access supply based on the ARA's recommended criteria. Most patients will need to switch to other medicines to conserve supply for patients with no or limited alternatives.
 - If the patient is deemed eligible by the treating physician, the treating physician will need to complete an OSHP Eligibility Form.
 - The completed OSHP Eligibility Form should only be provided to patients by their treating physicians (Rheumatologist/Clinical Immunologist) not General Practitioners or Pharmacists.
 - If a patient alerts you to this process and the requirement of an OSHP Eligibility Form, please advise the patient to contact their prescribing Rheumatologist/Immunologist who will be able reassess their treatment. Patients who are prescribed an Orencia subcutaneous injection that have not been contacted by their specialist should be advised to speak to their prescribing rheumatologist/immunologist as soon as possible.
- 2) When presented with an OSHP Eligibility Form, Pharmacists will need to:
 - **Complete specified Pharmacist section of the OSHP Eligibility Form and email the Form** along with the order to DHL
 - If the requested subcutaneous presentation is available, expect 3-5 days for delivery depending on weekday and pharmacy location
 - If the requested subcutaneous presentation is NOT available, DHL will communicate supply issues. Discuss options with patient including substitution under the TGA Serious Scarcity Substitution Instrument if appropriate

Note: updated ordering instructions are provided on page 3 of this letter.

BMS/DHL will notify you via email/iStore when the OSHP Eligiblity Form is no longer required.

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BMS is making every effort to resolve the situation as early as possible. We continue to work closely with TGA, ARA and Arthritis Australia to minimise the impact of the shortage on Australian patients.

For enquires please contact:

DHL Ordering 1800 077 421 d2mcs@dhl.com BMS Medical information 1800 067 567 medinfo.australia@bms.com

We thank you for your support and appreciate your patience during this period of constrained supply.

Yours sincerely,

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Meredith Edwards Medical Director Bristol-Myers Squibb Australia

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Orencia Stock Hypercare Plan (OSHP) Ordering Process For Pharmacists

Effective from Monday 22 April 2024 until further notice.

Due to limited stock of Orencia (abatacept) 125mg/mL prefilled syringe and ClickJect prefilled autoinjector, the Australian Rheumatology Association (ARA) has recommended that this stock be conserved for patients who meet certain eligibility criteria.

Bristol Myers Squibb (BMS) has developed a process to facilitate ordering for eligible patients called the Orencia Stock Hypercare Plan (OSHP).

Ask patient for their OSHP Eligibility Form

which is provided by their treating physician (being a Rheumatologist or Clinical Immunologist)

- Eligible patients must have a form and script filled out by their treating physician
 - the patient may give you their OSHP Eligibility Form, or it may be emailed by their treating physician
- If the patient does not have the form, advise that they contact their treating physician to reassess their treatment.
 Most patients will need to switch to other medicines. Patients who cannot switch to other medicines during the shortage will receive an OSHP Eligibility Form from their treating physician with the physician fields completed.

Once the OSHP Eligibility Form is received, place the Orencia (abatacept) order

- · Complete specified Pharmacist section of the form and
 - Email order and OSHP Eligibility Form to DHL at d2mcs@dhl.com
 - o Include 'OSHP' in the email subject line
 - o Include Pharmacy name, Account number, Product Description, SKU number and Quantity
 - Only one unit per patient per order, with one repeat a month
 - DO NOT include the patient's script in the email

Subcutaneous presentation availability

- Requested subcutaneous presentation available: 3-5 days for delivery depending on weekday and pharmacy location
- Requested subcutaneous presentation NOT available:
 o DHL will communicate supply issues.
 - Discuss options with patient, including substitution under the TGA Serious Scarcity Substitution Instrument if appropriate.

Patient support

- Direct patient to the Orencia GO website for resources and videos on how to administer Orencia
 Website: bms.com/au/gated/OrenciaGO Password: BMSGO
- Alternatively, resources on the Orencia GO website which includes the Australian Product Information, Consumer Medicine Information and the Orencia Patient Booklet can be printed to provide to patients.
- Ask the patient to keep their OSHP Eligibility Form and bring it with them when their next script repeat is required
- Alternatively, keep the OSHP Eligibility Form on record for use when ordering future repeats for the patient

For enquires please contact

DHL Ordering 1800 077 421 | d2mcs@dhl.com BMS Medical Information 1800 067 567 | medinfo.australia@bms.com