STELARA® (ustekinumab) Access Programme

1 November 2022

Re: STELARA® (ustekinumab) Access Programme

As you may already be aware, the recent PHARMAC proposal on the funding of STELARA closed on 26 October 2022. If the proposal is confirmed, funding would commence as of 1 February 2023.

Janssen wish to advise that a decision has been made to open a STELARA Access Programme for adult New Zealand patients with Crohn's disease or ulcerative colitis, who have been treated previously with either infliximab or adalimumab. This is subject to eligibility criteria and terms and conditions.

The programme will provide early access to STELARA for New Zealand patients who require immediate initiation on an additional biologic therapeutic option ahead of, what is hoped to be, a funded status for STELARA as of 1 February 2023.

This programme provides an important opportunity for a broader range of NZ clinicians to gain additional experience and familiarity in treating patients with STELARA within the New Zealand healthcare system (i.e., to aid in IV protocol development) as well as providing immediate access for patients in need.

Important information

1. Patient enrolments must be completed by the treating clinician at www.janssenpro.co.nz
2. Enrolments are subject to approval and must meet the enclosed criteria which is aligned with the proposed PHARMAC Special Authority criteria
3. Terms and conditions apply, please see enclosed
4. Patients are enrolled on the understanding that they will transition from the Access Programme to the publicly funded schedule (subject to funding being publicly notified and confirmed) as of 1 February 2023.

FAQ:

How long will patients be able to stay enrolled in the STELARA Access Programme?

Janssen will provide STELARA to patients enrolled in the STELARA programme until the earlier of the patient becoming eligible to access STELARA via a funded pathway or the patient discontinues treatment.

Janssen reserves the right to discontinue supply of STELARA if:

- STELARA is deregistered, discontinued, or divested; and/or
- There is a safety issue, recall, or any other regulatory action in respect to the product; and/or
- There is limited or no availability of STELARA

How many patients can be enrolled in the STELARA Access Programme?
There is no limit to the number of patients who can be enrolled. Enrolments are subject to approval and must meet enclosed eligibility criteria aligned with the proposed Pharmac Special Authority criteria. Terms and conditions apply.

If you have any further questions please feel free to contact Gene Pateman, Associate Director Medical Affairs, (gpateman@its.jnj.com) or Hayden Paul, Commercial lead, (hpaul1@its.jnj.com) at your convenience.

STELARA® (ustekinumab) Access Programme Eligibility criteria

Patients enrolled in the STELARA Access Programme must meet the following criteria:

1. Patient has moderate to severe active Crohn's disease and has luminal disease; **or**
2. Patient has histologically confirmed ulcerative colitis
3. For Crohn's patients the following criteria must be met:
    a. Any of the following:
        i. Patient is 18 years or older has a Crohn's disease Activity Index (CDAI) score of greater than or equal to 300; or Harvey Bradshaw Index (HBI) greater than or equal to 10; **or**
        ii. Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; **or**
        iii. Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; **or**
        iv. Patient has an ileostomy or colostomy, and has intestinal inflammation; **and**
    b. Patient has tried but had an inadequate response to (including lack of initial response and/or loss of initial response), or has experienced intolerable side effects from, adalimumab and/or infliximab; **and**
    c. Surgery (or further surgery) is considered to be clinically inappropriate.
4. For ulcerative colitis patients the following criteria must be met:
    a. Patient is 18 years or older and has a SCCAI score greater than or equal to 4; **and**
    b. Patient has tried but had an inadequate response to (including lack of initial response and/or loss of initial response), or has experienced intolerable side effects from, adalimumab and/or infliximab; **and**
    c. Surgery (or further surgery) is considered clinically inappropriate.

STELARA® (ustekinumab) Access Programme Terms and Conditions

In registering for the STELARA Access Programme and in enrolling any patient, you must agree to and comply with the following terms and conditions:

1. All Information provided in this form is correct;
2. STELARA supplied is only to be prescribed and used for the patient unless otherwise advised by Janssen;
3. Prior to submitting this application, you acknowledge and agree that you have
    a) read and understood the Data Sheet;
    b) discussed with the patient the potential risks and nature of side effects;
    c) obtained informed patient consent where applicable;
    d) obtained all necessary approvals and fulfilled all requirements (including hospital pharmacy requirements) relating to the prescription, supply and/or administration of STELARA
4. Janssen will continue to provide STELARA to existing patients enrolled in the STELARA Access Programme (enrolled prior to 1 November 2022) until the earlier of the patient becoming eligible to access STELARA via a funded pathway or the patient discontinues treatment;
5. Janssen will provide STELARA to new patients enrolled in the STELARA Access Programme (enrolled after 1 November 2023) until the earlier of the patient becoming eligible to access STELARA via a funded pathway or the patient discontinues treatment;
6. Janssen will supply STELARA to patients enrolled in the Access Programme free of charge to your Institution. Any costs associated with treatment of the patient or administration of STELARA are to be met by the patient or the institution;
7. Janssen reserves the right to discontinue or suspend the STELARA Access Programme for new and enrolled patients in the event that:
    a) STELARA is deregistered, discontinued or divested;
    b) There is a safety issue, recall, or any other regulatory action in respect of the product; or
    c) There is limited or no availability of STELARA.

    Janssen will use reasonable efforts to limit the impact of such events on the STELARA Access Programme;
8. You will notify Janssen if a patient ceases treatment with STELARA for any reason;
9. You will report any suspected adverse events, special situations and product complaints for Janssen products to Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com (quoting programme reference “PAPONC004888”) and as applicable to the New Zealand Pharmacovigilance Centre at https://nzphvc.otago.ac.nz/report/.
10. You agree to indemnify and hold harmless Janssen, against any loss, claim, liability or damage of any kind in relation to the accuracy or completeness of any Information given, or any representations made to the patient arising out of or relating to a failure to comply with the above obligations or the dispensing of the drug to the patient.

11. Janssen will collect use and disclose personal information you submit here as necessary to fulfil your request and in accordance with our Privacy policy, Accessible at https://www.janssenpro.com.nz/privacy-policy and you hereby consent to this collection, use and disclosure.
12. We also collect information about you to help us to understand you and your practice better, along with other information we collect from your interactions with us and from external sources like government and information brokers. This allows us to provide you with more relevant and useful information and better manage our relationship with you.
13. You consent for Janssen to use information you submit here for each of the purposes described under "How we use and disclose information" in our Privacy Policy and in consolidated and aggregated non-identifiable format for purposes including (i) to provide insights into product use; (ii) regulatory or reimbursement submissions; (iii) published in journals or presented at medical conferences.

STELARA® ustekinumab (rmc) MINIMUM DATA SHEET. STELARA® is an unfunded medicine – a prescription charge will apply**. INDICATIONS: Plaque Psoriasis:** Moderate to severe plaque psoriasis in adults (18 years or older) who are candidates for photo- or systemic therapy. **Psoriatic Arthritis (PsA):** STELARA, alone or in combination with methotrexate, is indicated for the treatment signs and symptoms, including reduction of the rate of progression of peripheral joint damage as measured by X-ray, of active psoriatic arthritis in adult patients (18 years or older). **Crohn's Disease:** moderately to severely active Crohn's disease in adult patients who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Ulcerative Colitis:** Moderate to severely active ulcerative colitis in adult patients. **DOSE: Psoriasis:** Subcutaneous injection. 45 mg at Weeks 0 and 4, then every 12 weeks. Alternatively, in patients weighing >100 kg, 90 mg at Weeks 0 and 4, then every 12 weeks. If inadequate response, consider treatment every 8 weeks. Discontinue if no response after 28 weeks. **Psoriatic Arthritis:** Subcutaneous injection. 45 mg at Weeks 0 and 4, then every 12 weeks. Alternatively, in patients weighing >100 kg, 90 mg at Weeks 0 and 4, then every 12 weeks. **Crohn's Disease & Ulcerative Colitis:** Single initial intravenous tiered dose based on body weight using STELARA 130 mg vial (weight ≤ 55kg = 260 mg [2 vials]; weight > 55kg to ≤ 85 kg = 390 mg [3 vials]; weight > 85 kg = 520 mg [4 vials]). Then subcutaneous injection of 90 mg 8 weeks after the intravenous dose, then every 8 weeks. In some patients a subcutaneous dose of 90 mg 8 weeks after the intravenous dose, then every 12 weeks may be acceptable according to clinical judgment. Consider discontinuing if no evidence of benefit by Week 16. Refer to full Data Sheet. **CONTRAINDICATIONS:** Hypersensitivity to ustekinumab or to any of the excipients. **PRECAUTIONS: Serious infections**: STELARA may increase risk of infections and reactivate latent infections. Serious bacterial, fungal and viral infections have been observed. Do not administer to patients with a clinically important active infection. Use with caution in patients with chronic or recurrent infections. **Tuberculosis (TB)**: Evaluate for TB prior to initiating treatment. Do not administer to patients with active TB. Treat latent TB before administration. Consider anti-TB therapy in patients with suspected TB. Monitor patients for TB. **Malignancies**: STELARA may increase risk of malignancies. Malignancies have been observed. Use with caution in patients with known malignancy or history of malignancies. **Hypersensitivity reactions**: Discontinue immediately if serious allergic reaction (including angioedema / anaphylaxis) occurs. **Immunisations**: Do not give live bacterial or viral vaccines. Consider secondary transmission of live vaccines from contacts. **Infant exposure in utero:** Do not administer live vaccines to infants who have been exposed in utero for 6 months following birth, unless they are exposed in first trimester only, or if ustekinumab levels are undetectable in the infant or if benefit of vaccination outweighs risk. **Immunosuppression**: Use in caution with immunosuppressive agents or when transitioning from other biologic agents. **Immunotherapy:** Use with caution in patients receiving allergy immunotherapy. **Posterior Reversible Encephalopathy Syndrome (PRES)**: Monitor and if PRES is suspected, STELARA should be discontinued and appropriate treatment administered. **Serious Skin Conditions:** Physicians should be alert for symptoms of erythrodermic psoriasis or exfoliative dermatitis in psoriasis patients. **General:** Pre-filled syringe needle cover contains dry natural rubber (latex) which may cause allergic reactions. **Use in Pregnancy**: Category B1. **INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS:** Live vaccines; On initiation of STELARA in patients receiving concomitant CYP450 substrates with a narrow therapeutic index, monitoring for therapeutic effect (e.g. for warfarin) or drug concentration (e.g. for cyclosporine) should be considered and the individual dose of the drug adjusted as needed. See full Data Sheet. **ADVERSE EFFECTS:** Upper respiratory tract infections; nasopharyngitis; dizziness; headache; oropharyngeal pain; diarrhoea; nausea; vomiting; pruritus; back pain; myalgia; arthralgia; fatigue; injection site erythema; injection site pain, serious infections, sinus infection; malignancies; depression and suicidality; hypersensitivity reactions including anaphylaxis and angioedema. See full Data Sheet. **Medicine Classification:** Prescription Medicine **PRESENTATION:** STELARA is a Prescription Medicine containing ustekinumab in packs of 1 single use 45mg pre-filled syringe; or 90mg pre-filled syringe each for subcutaneous use. For initiation dose in Crohn's Disease and Ulcerative colitis only: A pack of 1 single use 130 mg/5 mL vial for intravenous infusion. **STORAGE:** Store at 2°C – 8°C. Refrigerate. Do not freeze or shake.

Protect from light by storing in original carton. If needed, STELARA pre-filled syringes can be stored at room temperature up to 30°C for one period of time up to 30 days, not exceeding the original expiry. Before prescribing, please review full Data Sheet available from: https://www.janssen.com/newzealand/sites/www_janssen_com_newzealand/files/prod_files/live/stelara_data_sheet.pdf or www.medsafe. govt.nz. Janssen-Cilag (New Zealand) Ltd, 507 Mount Wellington Hwy, Mount Wellington, Auckland 1060, New Zealand. Date of preparation: 7 September 2022.
Material Preparation Date: October 2022**. CP-292390. TAPS NP18569.**