Prescribing Protocol SESLHDPR/611
Ustekinumab for Crohn's Disease

Prescribing Protocol	
Title	**Ustekinumab for Crohn's Disease**
Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward	Ambulatory care, peri-operative units, gastroenterology wards.
Areas where Protocol/Guideline not applicable	Non-gastroenterology wards
Authorised Prescribers	Gastroenterologists
Indication for use	Treatment of adult patients with moderately to severely active Crohn's disease in accordance with PBS criteria.
Clinical condition	Patients with moderate severe Crohn's disease 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. For detailed requirements see: http://www.pbs.gov.au/medicine/item/11164N-11182M
Place in Therapy	Prescribed after oral steroids and oral immunomodulators. in line with PBS requirements

Precautions	**Infection** Caution should be exercised when considering the use of ustekinumab in patients with a chronic infection or a history of recurrent infection. Stop treatment if severe infection occurs. Prior to initiating treatment, patients should be evaluated for tuberculosis (TB) infection. May reactivate inactive hepatitis B and latent TB (begin TB treatment before starting ustekinumab). **Malignancy** Do not use in active malignancy, use with caution in patients with a history of malignancy. **Serious skin conditions** In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment. **Pregnancy/breastfeeding** Avoid use in pregnancy. Ensure effective contraception until at least 15 weeks after the last dose. Manufacturer does not recommend breastfeeding during, and for up to 15 weeks after, treatment. Refer to Stelara® Product Information if more detail is required.
Dosage (Include dosage adjustment for specific patient groups)	Induction dose via a SINGLE intravenous infusion. The recommended treatment regimen is to initiate ustekinumab with a single intravenous (IV) dose based on body weight. The infusion solution is to be composed of the number of vials of ustekinumab 130 mg as specified below. Dose (number of 130 mg ustekinumab vials) based on body weight: ≤ 55 kg - 260 mg - 2 vials > 55 kg to ≤ 85 kg - 390 mg – 3 vials > 85 kg - 520 mg - 4 vials After the initial IV dose, ustekinumab should then be administered subcutaneously at a standard dose of 90mg. The first subcutaneous dose should be administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter. If response is adequate, consider giving every 12 weeks.
Duration of therapy	Every 8-12 weeks indefinitely according to response

Important Drug Interactions	**Live vaccines** should not be given concurrently (see precautions) **CYP450 substrates** (e.g. warfarin, ciclosporin) - monitoring for therapeutic effect or drug concentration should be considered and the individual dose of the drug adjusted as needed. **Immunosuppression:** Caution should be exercised when considering concomitant use of immunosuppressive agents and ustekinumab or when transitioning from other biologic agents. Immunotherapy Allergy immunotherapy: ustekinumab may affect allergy immunotherapy. Caution should be exercised in patients receiving or who have received allergy immunotherapy particularly for anaphylaxis.

Administration instructions	**For single IV dose administration (induction dose):** 1. Calculate the dose and the number of ustekinumab 130mg vials needed based on the patient's weight. 2. Withdraw, and then discard, an equivalent volume from the 250 mL infusion bag, to the volume of ustekinumab to be added (26mL per 130mg vial) e.g. 2 vials = 52 mL 3 vials = 78 mL 4 vials = 104 mL 3. Withdraw 26mL of ustekinumab from each vial needed and add it to the 250 mL infusion bag. The final volume of the bag should be 250mL.Gently mix. 4. Visually inspect the diluted infusion solution before administration. Do not use if visibly opaque particles, discolouration, or foreign particles are observed. 5. Infuse the diluted infusion solution over a period of at least 1 hour. Once diluted, the infusion solution may be stored for up to 4 hours (at room temperature, up to 25°C) prior to infusion. 6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer) 7. Do not infuse ustekinumab concomitantly in the same IV line with other agents. 8. Ustekinumab solution for injection does not contain preservatives. Each vial is for single use only. Discard any remaining solution. Dispose of any unused medicinal product in accordance with local requirements **After the initial IV dose, ustekinumab should then be administered subcutaneously**. The first subcutaneous dose of 90 mg (2 x 45mg vials) should be administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
Monitoring requirements	Monitor for hypersensitivity reactions during and immediately post-administration, e.g. rash, urticaria (rarely angioedema, anaphylaxis)
Safety	Monitor for adverse drug reactions, including: infections, dizziness, headache, fatigue, diarrhoea, itch, arthralgia, myalgia, pain, injection site reactions, malignancies, pustular psoriasis, exfoliative dermatitis
Effectiveness	Monitor CDAI score and biomarkers to ensure adequate response to treatment. Stop ustekinumab if there is no clinical response by week 16.

Management of complications	If an anaphylactic or other serious hypersensitivity reaction occurs, appropriate supportive therapy should be instituted and administration of should be discontinued immediately. Other adverse reactions should be managed supportively with consideration for discontinuing treatment based on risk/benefit assessment.
Basis of Protocol/Guideline: (including sources of evidence, references)	Stelara® Product Information Stelara® Infusion Protocol Australian Medicines Handbook
Groups consulted in development of this guideline	SESLHDQUM Committee

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GOVERNANCE	
Enactment date	March 2018
Expiry date: (maximum 36 months from date of original approval)	March 2021
Ratification date by Drug Committee	1 March 2018
Protocol/Guideline Number	SESLHDPR/611
Version Number	1