

Reimbursement of Medicinal Products containing Ustekinumab: Questions and Answers for Healthcare Professionals June 2026

Introduction

As of 1 June 2026, there are seven medicinal products containing ustekinumab on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement:

- Imuldosa[®] solution for injection (Accord Healthcare Ireland Limited)
- Otulfi[®] solution for injection (Fresenius Kabi Ireland)
- Pyzchiva[®] solution for injection (Sandoz Limited trading as Rowex)
- Stelara[®] solution for injection (Johnson & Johnson Innovative Medicine)
- Steqeyma[®] solution for injection (Celltrion Healthcare Ireland Limited)
- Uzpruvo[®] solution for injection (Clonmel Healthcare Limited)
- Wezenla[®] solution for injection (Amgen Ireland Limited).

Stelara[®] is the reference biological medicine; Imuldosa[®], Otulfi[®], Pyzchiva[®], Steqeyma[®], Uzpruvo[®] and Wezenla[®] are biosimilar medicines of Stelara[®].

All seven medicinal products are available in a pre-filled syringe presentation, containing 45 milligrams (mg) or 90 mg of ustekinumab. Pyzchiva[®], Stelara[®] and Wezenla[®] are also available in a pre-filled pen presentation, containing 45 mg or 90 mg of ustekinumab. Stelara[®] and Wezenla[®] are available in a solution for injection vial presentation, containing 45 mg of ustekinumab per vial; this presentation facilitates subcutaneous administration for the treatment of plaque psoriasis in paediatric patients weighing less than 60 kilograms (kg), who need to receive less than the 45 mg dose.

All seven medicinal products are also available in a concentrate for solution for infusion vial presentation, containing 130 mg of ustekinumab. This presentation is supplied and administered in the hospital setting.

In December 2025, following a review of medicinal products containing ustekinumab, the HSE-Medicines Management Programme (MMP) recommended the following as best-value biological (BVB) medicines for ustekinumab:

- **Imuldosa**[®] (Accord Healthcare Ireland Limited)
- **Otulfi**[®] (Fresenius Kabi Ireland)
- **Pyzchiva**[®] (Sandoz Limited trading as Rowex)
- **Wezenla**[®] (Amgen Ireland Limited).

In May 2026, the MMP identified an additional BVB medicine for ustekinumab:

- **Uzpruvo**[®] (Clonmel Healthcare Limited).

Evaluation reports, which include information on the process followed to identify the BVB medicines, are available on the website of the MMP under *Best-Value Medicines*: www.hse.ie/mmp.

The MMP may recommend additional BVB medicines for ustekinumab in 2026.

I am initiating a patient on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn’s disease; what should I do in light of the BVB medicine recommendations?

The MMP recommends that all new patients being initiated on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn’s disease should be prescribed a BVB medicine.

Accord Healthcare Ireland Limited, Amgen Ireland Limited, Clonmel Healthcare Limited, Fresenius Kabi Ireland and Sandoz Limited trading as Rowex have confirmed that sufficient stock of their biosimilar medicines containing ustekinumab is available to support an uplift in demand arising from the MMP BVB medicine recommendations.

What is the situation for patients currently in receipt of a medicinal product containing ustekinumab on the High Tech Arrangement?

There is currently no change for existing patients. They will continue to receive their medicine on the High Tech Arrangement from their community pharmacy.

At this point in time, all valid High Tech prescriptions for medicinal products containing ustekinumab on the HSE Reimbursement List remain eligible for reimbursement on the High Tech Arrangement.

The MMP recommends that patients currently established on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease should be considered for switching to a BVB medicine at the earliest possible opportunity.

In recognition of the efficiencies that result from the prescribing of the BVB medicine, a gainshare arrangement is available to consultant-led teams in public hospitals who switch patients established on treatment with ustekinumab on the High Tech Arrangement, to a BVB medicine for ustekinumab. Gainshare funds will be used to fund service delivery and enhancements in areas that are responsible for generating the savings.

Are changes being introduced in relation to the reimbursement of ustekinumab on the High Tech Arrangement?

At present, no changes are being introduced in relation to the reimbursement of ustekinumab on the High Tech Arrangement.

The HSE-MMP has identified BVB medicines for ustekinumab; **Imuldosa**[®], **Otulf**[®], **Pyzchiva**[®], **Uzpruvo**[®] and **Wezenla**[®]. The MMP recommends that:

- all new patients being initiated on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease should be prescribed a BVB medicine
- patients currently established on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease should be considered for switching to a BVB medicine at the earliest possible opportunity.

The MMP will monitor uptake of the recommended BVB medicines; the introduction of additional measures to support prescribing of the BVB medicines may be considered to ensure uptake is optimised.

What are the benefits of prescribing the BVB medicine for ustekinumab?

The BVB medicines for ustekinumab are provided to the HSE at a much lower cost than other medicinal products containing ustekinumab. This provides an opportunity to reduce the cost to the HSE of providing these medicines to patients.

Funding to facilitate access to new medicines for patients in 2026 is dependent on the delivery of savings from within the medicines budget. Prescribing of BVB medicines reduces the financial burden on the HSE arising out of the funding of reimbursed medicines, and therefore can assist in securing ongoing access for patients to new, innovative medicines.

Are the best-value biological medicines for ustekinumab licensed for the treatment of ulcerative colitis?

At present, none of the biosimilar medicines on the HSE Reimbursement List for prescribing and supply on the High Tech Arrangement or with hospital pricing approval, are licensed for the treatment of ulcerative colitis.

The reference biological medicine (Stelara®) is licensed for the treatment of adult patients with moderately-to-severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic.

The aim of the BVB medicine initiative is to ensure that the efficiencies presented by the availability of biosimilar medicines for ustekinumab are fully realised to achieve best value. The BVB medicine evaluation process for ustekinumab therefore focused on the therapeutic indications of ustekinumab for which biosimilar medicines of ustekinumab are licensed. Licensed indications of the reference medicine, for which biosimilar medicines are not licensed, fell outside the scope of the BVB medicine evaluation process for ustekinumab.

Where can I get information on the best-value biological medicine for ustekinumab?

Information on the BVB medicine is available on the website of the MMP under *Best-value medicines*: www.hse.ie/mmp.

This includes support materials for clinical teams who are initiating patients on, or switching them to the BVB medicine:

- Reimbursement of Medicinal Products containing Ustekinumab: Questions and Answers for Healthcare Professionals
- BVB Ustekinumab – Questions and Answers for Healthcare Professionals
- Information for Patients about Medicines containing Ustekinumab
- MMP product information sheets for Imuldosa[®], Otulfi[®], Pyzchiva[®], Uzpruvo[®] and Wezenla[®]
- Information on patient support services for Imuldosa[®], Otulfi[®], Pyzchiva[®], Uzpruvo[®] and Wezenla[®]
- Template switching letter for clinics.

Who should I contact if I have any questions?

The MMP are available to engage with consultants and clinical teams to support prescribing of the BVB medicines via the High Tech Hub. This includes the provision of information sessions, in conjunction with the High Tech Co-ordination Unit, on the BVB medicine and the High Tech Hub. Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

Imuldosa[®], Otulfi[®], Pyzchiva[®], Uzpruvo[®] and Wezenla[®] are biosimilar medicines containing ustekinumab; where can I get more information on biosimilar medicines?

Further information for both healthcare professionals and patients on biosimilar medicines is available on the following websites:

Health Products Regulatory Authority (HPRA): www.hpra.ie/regulation/human-medicine/patients-and-healthcare-professionals/biosimilar-medicines

European Medicines Agency (EMA): www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section

The HSE-Access & Integration Drug Management Programme (AIDMP) has published guidance for biological and biosimilar medicine use in acute hospitals (version 2, May 2024). The guidance states that for a biological medicine with a biosimilar available for the same licensed indication, the medicine offering the better value should be prescribed. It also recommends that all treatment-naïve patients should be initiated on the better-value medicine (whether biosimilar or reference medicine).

The European Medicines Agency issued a joint statement with the Heads of Medicines Agencies on interchangeability of biosimilar medicines in September 2022. What did this say?

This statement confirmed that biosimilar medicines approved in the European Union are interchangeable with their reference medicine or with an equivalent biosimilar medicine.

Interchangeability in this context means that a prescriber can replace the reference medicine with a biosimilar medicine without a patient experiencing any changes in the clinical effect.

The EMA highlighted that the experience obtained from clinical practice has shown that in terms of efficacy, safety and immunogenicity, biosimilar medicines are comparable to their reference medicine and therefore can be prescribed interchangeably.

Can medicinal products containing ustekinumab be prescribed on the High Tech Hub?

Yes, prescriptions for medicinal products containing ustekinumab can be generated on the High Tech Hub.

Since August 2020, the High Tech Hub has been approved as a national electronic prescription transfer system.

Queries in relation to registration for the High Tech Hub should be directed to the HSE-Primary Care Reimbursement Service (PCRS) High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

When switching a patient to a BVB medicine for ustekinumab (Imuldosa[®], Otulfi[®], Pyszchiva[®], Uzpruvo[®] or Wezenla[®]), the prescription must be generated on the High Tech Hub in order to be eligible for the gainshare arrangement.