Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim
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12th January 2026

Circular 001/26

RE: BVB Medicine Ustekinumab

Dear Pharmacist,

Please find enclosed a copy of a letter and supporting FAQs issued to prescribing consultants by the HSE Medicines Management Programme (MMP) in relation to the Best-Value Biological (BVB) Medicine for Ustekinumab under the High Tech Arrangement.

Your cooperation with this important HSE initiative is appreciated.

Yours faithfully,

Shaun Flanagan
Assistant National Director
Primary Care Reimbursement Service

Re: Best-Value Biological Medicines – Ustekinumab

19 December 2025

Dear Colleagues,

I am writing to inform you that the HSE-Medicines Management Programme (MMP) has completed a review of the medicinal products containing ustekinumab, and is now recommending best-value biological (BVB) medicines.

Expenditure on medicinal products containing ustekinumab on the High Tech Arrangement was approximately €63.1 million in 2024. Additional expenditure was incurred in the hospital setting arising from administration of medicinal products containing ustekinumab. There are now biosimilar medicines containing ustekinumab available on either the HSE Reimbursement List for prescribing and supply on the High Tech Arrangement, or with Hospital Pricing Approval; the MMP recognises the potential savings arising from these. These savings, however, can only be realised by prescribing and utilisation of the recommended BVB medicines.

The MMP recommends the following as BVB medicines for ustekinumab:

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

The following presentations of the BVB medicines are available on the HSE Reimbursement List:

- Pre-filled syringe presentation, containing 45 mg or 90 mg of ustekinumab: Imuldosa®, Otulfi®, Pyzchiva® and Wezenla®
- Pre-filled pen presentation, containing 45 mg or 90 mg of ustekinumab: Pyzchiva® and Wezenla®
- Solution for injection vial presentation, containing 45 mg of ustekinumab per vial: Wezenla®. This presentation facilitates subcutaneous administration for the treatment of plaque psoriasis in paediatric patients weighing less than 60 kg, who need to receive less than the 45 mg dose.

All four BVB medicines are available in a concentrate for solution for infusion vial presentation containing 130 mg of ustekinumab.

An evaluation report entitled **Best-value biological medicine: Ustekinumab** is available at www.hse.ie/mmp in the section entitled *Best-value medicines*. In this report, 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.

Accord Healthcare Ireland Limited, Amgen Ireland 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.

Non-BVB Medicines

Non-BVB medicines for ustekinumab on the HSE Reimbursement List (e.g. Stelara®) are substantially more expensive than the recommended BVB medicines.

In September 2022, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) issued a joint statement on interchangeability of biosimilar medicines. This 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.

In light of the EMA/HMA joint statement on interchangeability and the substantial difference in cost between the recommended BVB medicines and non-BVB medicines, all patients who are currently prescribed ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease on the High Tech Arrangement should be considered for switching to a BVB medicine at the earliest possible opportunity.

Gainshare Arrangement

In recognition of the efficiencies that result from the prescribing of the BVB medicines, a gainshare arrangement is available from 1 January 2026 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. Under this arrangement, €500 of the savings accruing per patient will be made available to the public hospital responsible for the saving in the first instance. The prescription for ustekinumab must be generated on the High Tech Hub.

The gainshare arrangement will remain in place until 31 December 2026. The process for release of gainshare funds will be aligned with that previously employed for adalimumab and etanercept. Queries in relation to the release of gainshare funds should be directed to the HSE-Primary Care Reimbursement Service High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

High Tech Hub Enhancement

The High Tech Hub has been enhanced to support clinical teams to identify patients who are established on treatment with non-BVB medicines (e.g. Stelara®). A search function has been added to the *My Patients* tab; this allows clinical teams to search for prescriptions generated on the High Tech Hub by INN or medicinal product within a specified timeframe. This will facilitate timely identification of patients who remain on a non-BVB medicine.

A step-by-step guide on how to use this search function to identify patients who remain on a non-BVB medicine is included with this communication.

Support for Clinical Teams

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

Please find enclosed Questions and Answers document for Healthcare Professionals, and information for patients. Further information on this initiative, including information for healthcare professionals and resources to support initiating patients on, or switching them to, the recommended BVB medicines are available on the MMP website (www.hse.ie/mmp) in the section entitled *Best-value medicines*.

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.

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.

I would ask that you support this important initiative, which helps to secure ongoing access for patients to new and innovative medicines.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
HSE-Medicines Management Programme.

Reimbursement of Medicinal Products containing Ustekinumab: Questions and Answers for Healthcare Professionals December 2025

Introduction

As of 1 December 2025, 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 treading 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 mg or 90 mg of ustekinumab or syringe. 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 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) recommends the following as BVB medicines for ustekinumab:

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

An evaluation report, which includes information on the process followed to identify the BVB medicine, is 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, 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®**, **Otulfi®**, **Pyzchiva®** 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 medicine; the introduction of additional measures to support prescribing of the BVB medicine 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 of 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 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® and Wezenla®
- Information on patient support services for Imuldosa®, Otulfi®, Pyzchiva® 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® 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: www.hpra.ie/regulation/human-medicine/patients-and-healthcare-professionals/biosimilar-medicines

European Medicines Agency: 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 High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

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

Information for Patients about Medicines containing Ustekinumab

December 2025

Ustekinumab is a biological medicine used to treat inflammatory conditions such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. Biological medicines are medicines made or derived from living cells, and they are widely used in the treatment of many conditions.

Ustekinumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body. Ustekinumab works by blocking the chemical messengers interleukin-12 and interleukin-23, which can cause inflammation. Ustekinumab reduces inflammation and associated signs and symptoms of the condition.

When used in the treatment of plaque psoriasis and psoriatic arthritis, ustekinumab is usually administered by injection under the skin (subcutaneous injection) at week 0, week 4 and then every 12 weeks thereafter. When starting treatment for Crohn's disease or ulcerative colitis, the initial dose is given as an infusion via a drip in hospital, followed by subcutaneous injection every 8 to 12 weeks.

The subcutaneous injection of ustekinumab is supplied to patients by their Community Pharmacy.

What are the best-value biological medicines for ustekinumab?

The best-value biological (BVB) medicines identified by the HSE for ustekinumab are:

- **Imuldosa®**
- **Otulfi®**
- **Pyzchiva®**
- **Wezenla®.**

Imuldosa®, Otulfi®, Pyzchiva® and Wezenla® are biosimilar medicines; what is a biosimilar medicine?

A biosimilar medicine is very similar to the original biological medicine. It works in the same way.

Stelara® was the original biological medicine for ustekinumab. Recently, biosimilar medicines containing ustekinumab became available. Imuldosa®, Otulfi®, Pyzchiva® and Wezenla® are biosimilar medicines of Stelara®.

Are biosimilar medicines safe?

Biosimilar medicines are tested to show they are just as safe and effective as the original biological medicine.

The original biological medicine (Stelara®) and the biosimilar medicines (e.g. Imuldosa®, Otulfi®, Pyzchiva® and Wezenla®) can cause similar side-effects.

Biosimilar medicines are also available for adalimumab, etanercept and infliximab. These biosimilar medicines are frequently prescribed by Dermatologists, Gastroenterologists, Rheumatologists, and their teams.

What's changing?

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

The HSE has identified BVB medicines for ustekinumab; Imuldosa®, Otulfi®, Pyzchiva® and Wezenla®.

The HSE 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.

I am an existing patient prescribed ustekinumab, what does this mean for me?

If you are an existing patient, you will continue to receive your medicine from your community pharmacy.

If you are currently on a non-BVB medicine of ustekinumab (e.g. Stelara®) for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease, your consultant or a member of their team may discuss the possibility of switching to a BVB medicine.

Has my consultant being informed about the best-value biological medicines?

Yes. Consultants in dermatology, gastroenterology and rheumatology are aware of the BVB medicines.

Biosimilar medicines are widely used by Dermatologists, Gastroenterologists Rheumatologists, and their teams.

Why is the HSE recommending a best-value biological medicine for ustekinumab?

The BVB medicines are provided to the HSE at a lower cost. Prescribing the BVB medicines will save the HSE money. This means we can give new innovative medicines to even more patients, including for the treatment of conditions in dermatology. gastroenterology and rheumatology.

What supports are available?

Supports for patients prescribed this medicine can include:

- nurse home visit to provide training on administering the injection
- supply of sharps bins and waste collection service
- provision of product information.

Your consultant or a member of their team will register you for these services.

Where can I get more information on biosimilar medicines?

Further information on biosimilar medicines and the BVB medicines is available on the following websites:

HSE-Medicines Management Programme: www.hse.ie/mmp under Best-value medicines

Health Products Regulatory Authority: www.hpra.ie/regulation/human-medicine/patients-and-healthcare-professionals/biosimilar-medicines/biological-and-biosimilar-medicines--what-patients-should-know

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