Re: Best-Value Biological Medicines – Tocilizumab

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 tocilizumab that are available on the High Tech Arrangement, and is now recommending a best-value biological (BVB) medicine.

Expenditure on medicinal products containing tocilizumab on the High Tech Arrangement was approximately €13.9 million in 2024. Biosimilar medicines containing tocilizumab are on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement; the MMP recognises the potential savings arising from these. These savings, however, can only be realised by prescribing and utilisation of the recommended BVB medicine.

The MMP recommends **Tyenne®** (Fresenius Kabi Ireland) as the BVB medicine for tocilizumab on the High Tech Arrangement. Tyenne® is available on the HSE Reimbursement List in pre-filled pen and syringe presentations, both containing 162 mg of tocilizumab.

An evaluation report entitled **Best-value biological medicine: Tocilizumab on the High Tech Arrangement** 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 treatment with tocilizumab on the High Tech Arrangement should be prescribed the BVB medicine
- patients currently established on treatment with tocilizumab on the High Tech Arrangement should be considered for switching to the BVB medicine at the earliest possible opportunity.

Fresenius Kabi Ireland have confirmed that sufficient stock of Tyenne® is available to support an uplift in demand arising from the MMP BVB medicine recommendations.

Non-BVB Medicines

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

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 medicine and non-BVB medicines, all patients who are currently prescribed a non-BVB medicine on the High Tech Arrangement (e.g. RoActemra®) should be considered for switching to the BVB medicine at the earliest possible opportunity.

Gainshare Arrangement
In recognition of the efficiencies that result from the prescribing of the BVB medicine, a gainshare arrangement is available from 1 January 2026 to consultant-led teams in public hospitals who switch patients established on treatment with tocilizumab on the High Tech Arrangement, to the BVB medicine for tocilizumab, Tyenne®. 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 tocilizumab 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. RoActemra®). 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 medicine 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 medicine; the introduction of additional measures to support prescribing of the BVB medicine 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 Tocilizumab: Questions and Answers for Healthcare Professionals
December 2025

Introduction

As of 1 December 2025, there are two medicinal products containing tocilizumab on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement:

- RoActemra® solution for injection (Roche Products Ireland Limited)
- Tyenne® solution for injection (Fresenius Kabi Ireland).

RoActemra® is the reference biological medicine; Tyenne® is a biosimilar medicine of RoActemra®.

Both medicinal products are available in pre-filled pen and pre-filled syringe presentations, containing 162 mg of tocilizumab per pre-filled pen or syringe.

In November 2025, following a review of medicinal products containing tocilizumab on the HSE Reimbursement List, the HSE-Medicines Management Programme (MMP) identified a best-value biological medicine (BVB) for tocilizumab on the High Tech Arrangement:

- **Tyenne®** solution for injection pre-filled pen / pre-filled syringe 162 mg (Fresenius Kabi Ireland).

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 tocilizumab on the High Tech Arrangement in 2026.

RoActemra® and Tyenne® are also available in concentrate for solution for infusion vial presentations. These presentations are supplied and administered in the hospital setting, and fell outside the scope of the BVB medicine evaluation process undertaken by the MMP.

I am initiating a patient on tocilizumab for supply on the High Tech Arrangement; what should I do in light of the BVB medicine recommendations?

The MMP recommends that all new patients being initiated on treatment with tocilizumab on the High Tech Arrangement should be prescribed the BVB medicine, Tyenne®.

Fresenius Kabi Ireland have confirmed that sufficient stock of Tyenne® 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 tocilizumab 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 tocilizumab on the HSE Reimbursement List remain eligible for reimbursement on the High Tech Arrangement.

The MMP recommends that patients currently established on treatment with tocilizumab on the High Tech Arrangement should be considered for switching to the 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 tocilizumab on the High Tech Arrangement, to the BVB medicine for tocilizumab. 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 tocilizumab on the High Tech Arrangement?

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

The HSE-MMP has identified a BVB medicine for tocilizumab on the High Tech Arrangement, **Tyenne®**. The MMP recommends that:

- all new patients being initiated on treatment with tocilizumab on the High Tech Arrangement should be prescribed the recommended BVB medicine
- patients currently established on treatment with tocilizumab on the High Tech Arrangement should be considered for switching to the 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 tocilizumab?

The BVB medicine for tocilizumab is provided to the HSE at a much lower cost than other medicinal products containing tocilizumab that are available for prescribing on the High Tech Arrangement. 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.

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

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 Tocilizumab: Questions and Answers for Healthcare Professionals
- BVB Tocilizumab – Questions and Answers for Healthcare Professionals
- Information for Patients about Medicines containing Tocilizumab
- MMP product information sheets for Tyenne®
- Information on patient support services for Tyenne®
- 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 medicine 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.

Tyenne® is a biosimilar medicine containing tocilizumab; 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 tocilizumab be prescribed on the High Tech Hub?

Yes, prescriptions for medicinal products containing tocilizumab 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 the BVB medicine for tocilizumab (Tyenne®), 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 Tocilizumab

December 2025

Tocilizumab is a biological medicine. Biological medicines are medicines made or derived from living cells, and they are widely used in the treatment of many conditions.

Tocilizumab blocks the action of a specific protein called interleukin-6. This is found in high levels in patients with inflammatory conditions such as Rheumatoid Arthritis. Blocking the action of interleukin-6 can reduce inflammation and other symptoms of these conditions such as pain.

Tocilizumab is administered by weekly injection under the skin (subcutaneous injection) or by monthly infusion (drip) in a hospital.

The subcutaneous injection of tocilizumab is supplied to patients by their Community Pharmacy. It is used for the treatment of inflammatory conditions, including Rheumatoid Arthritis and Giant Cell Arteritis in adults, and Juvenile Idiopathic Arthritis in children.

What is the best-value biological medicine for tocilizumab?

The best-value biological (BVB) medicine identified by the HSE for tocilizumab is:

- **Tyenne®.**

Tyenne® is a biosimilar medicine; what is a biosimilar medicine?

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

RoActemra® was the original biological medicine for tocilizumab. Recently, biosimilar medicines containing tocilizumab became available. Tyenne® is a biosimilar medicine of RoActemra®.

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 (RoActemra®) and the biosimilar medicine (Tyenne®) can cause similar side-effects.

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

What's changing?

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

The HSE has identified a BVB medicine for tocilizumab on the High Tech Arrangement, Tyenne®.

The HSE recommends that all new patients being initiated on treatment with tocilizumab on the High Tech Arrangement should be prescribed the recommended BVB medicine.

I am an existing patient prescribed tocilizumab, 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 (e.g. RoActemra®), 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 rheumatology are aware of the BVB medicines.

Biosimilar medicines are widely used by Rheumatologists and their teams.

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

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 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