Best-Value Biological Medicines:

Tocilizumab

Questions and Answers for Healthcare Professionals

1) What is a biological medicine?

A biological medicine is a medicine that contains an active substance made by a biological process or derived from a biological source.[1] Most biological medicines are produced from cell cultures of living organisms, such as mammalian cells, bacterial or yeast cells, which have been engineered to produce a specific therapeutic molecule or group of molecules, usually protein(s).[1] Biological medicines contain larger and more complex active substances than chemically synthesised small molecules and in general, tend to be more targeted in their therapeutic activity.[1] Tocilizumab is an example of a biological medicine.

2) What is a biosimilar medicine?

A biosimilar medicine is a biological medicine that is highly similar to another biological medicine (called the reference biological medicine) that has already been authorised for use in the European Union (EU).[1] The European Medicines Agency (EMA) list the following specific features of biosimilar medicines:[2]

- They are highly similar to the reference biological medicine
- There are no clinically meaningful differences compared with the reference biological medicine
- The variability between the biosimilar and the reference biological medicine is kept within strict limits
- The same strict standards of quality, safety and efficacy apply to the biosimilar as do to the reference biological medicine.

In relation to tocilizumab, Avtozma® and Tyenne® are examples of biosimilar medicines of the reference biological medicine, RoActemra®.

3) Why is a biosimilar medicine not a generic medicine?

As biological medicines are produced by living organisms, there is an inherent degree of natural variability that is not present with chemical entities. Due to this variability, it may not be possible to produce an exact copy of a reference biological medicine. As a result, generic versions of biological medicines are not feasible.[1,2]

Due to the natural variability of the biological source and to the manufacturing process unique to each manufacturer, minor differences can occur between the biosimilar medicine and the reference biological medicine. Strict controls are in place during the manufacturing process to ensure that the minor differences do not affect the way the biosimilar medicine works or its safety. These differences, therefore, are not clinically meaningful in terms of efficacy or safety.[2]

Biosimilar medicines are similar but not identical versions of their reference biological medicine. They have an overall degree of comparability to the reference biological medicine.[1]

4) Where can I find further information on biological and biosimilar medicines?

The Health Products Regulatory Authority (HPRA), and the European Commission and the EMA have published guidance documents on biosimilar medicines:

HPRA: https://www.hpra.ie/regulation/human-medicine/patients-and-healthcare-professionals/biosimilar-medicines

EMA: https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview

5) 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 EU are interchangeable with their reference medicine or with an equivalent biosimilar medicine.[3]

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.[3]

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.[3]

6) What are best-value biological (BVB) medicines?

The aim of the best-value biological (BVB) process is to ensure that the efficiencies presented by the availability of biosimilar medicines are fully realised to achieve best value.

Where biosimilar medicines become available for a biological medicine that is funded or reimbursed by the HSE, the Medicines Management Programme (MMP) may undertake a BVB medicine evaluation process and issue a recommendation as to the BVB medicines. The criteria that may be considered by the MMP in identifying a BVB medicine, and the evaluation process are outlined in Schedule 2 of the Framework Agreements for the Supply and Pricing of Medicines 2026 - 2029.[4,5]

7) Why is it important that a BVB medicine is identified and prescribed?

Biological medicines account for a significant amount of the total annual expenditure on medicines by the state. For example, nine of the twenty medicines with the highest expenditure* on the High Tech Arrangement in 2023 were biological medicines, accounting for expenditure* of approximately €348 million.[6]

Prescribing of BVB medicines will ensure that available efficiencies are realised and savings for the health service are achieved. It also 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.

* Expenditure reflects the ingredient cost of the medicinal product, exclusive of value-added tax and fees

Tocilizumab

In relation to medicinal products containing tocilizumab, the concentrate for solution for infusion presentation of the reference biological medicine, RoActemra®, first received a marketing authorisation in 2009. The pre-filled syringe and pre-filled pen presentations of RoActemra® were added to the HSE Reimbursement List on 1 February 2015 and 1 September 2018, respectively, for prescribing and supply on the High Tech Arrangement.

8) Are biosimilar medicines of tocilizumab now available?

In September 2023, Tyenne® was the first biosimilar medicine containing tocilizumab to receive a marketing authorisation from the European Commission, following consideration of a marketing authorisation application via the EMA centralised procedure. Three further biosimilar medicines containing tocilizumab, Avtozma®, Tocilizumab Stada® and Tuyory®, are now also licensed by the European Commission.

The pre-filled pen and pre-filled syringe presentations of Tyenne® 162 mg were added to the HSE Reimbursement List on 1 December 2023, for prescribing and supply on the High Tech Arrangement. Hospital pricing approval is in place for the concentrate for solution for infusion vial presentation of Tyenne®.

The pre-filled pen and pre-filled syringe presentations of Avtozma® 162 mg were added to the HSE Reimbursement List on 1 May 2026, for prescribing and supply on the High Tech Arrangement. Hospital pricing approval is in place for the concentrate for solution for infusion vial presentation of Avtozma®.

It is anticipated that further biosimilar medicines of tocilizumab may become available in Ireland in 2026.

9) What are the BVB Medicines for tocilizumab?

In November 2025, following a review of medicinal products containing tocilizumab on the HSE Reimbursement List, the MMP identified a BVB medicine for tocilizumab on the High Tech Arrangement:

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

In April 2026, the MMP identified an additional BVB medicine for tocilizumab on the High Tech Arrangement:

- **Avtozma®** solution for injection pre-filled pen / pre-filled syringe 162 mg (Celltrion Healthcare Ireland Limited).

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

The BVB medicines for tocilizumab are 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. 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.

10) How were the BVB medicines for tocilizumab identified?

The BVB medicines for tocilizumab were identified in line with the evaluation process outlined in the MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting.[7] The criteria that are considered by the MMP in identifying the BVB medicines are aligned with those included in Schedule 2 of the Framework Agreements for the Supply and Pricing of Medicines 2026 - 2029.[4,5]

Evaluation reports are available at www.hse.ie/mmp in the section entitled *Best-value medicines*.

11) What is the difference in cost between the reference biological medicine (RoActemra®) and the BVB medicines (Avtozma®, Tyenne®)?

The reimbursement prices of medicinal products containing tocilizumab on the HSE Reimbursement List, including biosimilar medicines, are available on the website of the HSE-Primary Care Reimbursement Service (PCRS); www.pcrs.ie. The reimbursement price listed may not represent the final acquisition cost of the medicinal product to the HSE, as it not does not include any rebates and commercial-in-confidence arrangements that are in place.

Non-BVB medicines for tocilizumab on the HSE Reimbursement List (e.g. RoActemra®) are substantially more expensive than the identified BVB medicines for tocilizumab. This is due to commercial-in-confidence arrangements that are in place with the HSE arising from the evaluation process for the BVB medicines. This provides an opportunity to reduce the cost to the HSE of providing these medicines to patients.

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.

12) When should the BVB medicines for tocilizumab (Avtozma®, Tyenne®) be prescribed?

The MMP recommends that:

- all new patients being initiated on treatment with tocilizumab on the High Tech Arrangement should be prescribed a recommended BVB medicine
- patients currently established on treatment with tocilizumab on the High Tech Arrangement 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 medicines, 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 a BVB medicine for tocilizumab (Avtozma® or Tyenne®).

Gainshare funds will be used to fund service delivery and enhancements in areas that are responsible for generating the savings.

From 1 July 2026, reimbursement of tocilizumab on the High Tech Arrangement for treatment-naïve individuals (i.e. individuals commencing treatment with tocilizumab) is only supported for BVB medicines, as identified by the MMP. All patients, therefore, who are commencing treatment with tocilizumab on the High Tech Arrangement should be prescribed a BVB medicine.

13) What supports are available for consultants and 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.

Resources to support prescribing of the BVB medicine are available on the MMP website (www.hse.ie/mmp) in the section entitled *Tocilizumab* under *Best-value medicines*. These include:

- 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 sheet for Avtozma® and Tyenne®
- Information on patient support services for Avtozma® and Tyenne®
- Template switching letter for clinics.

Support is also available for clinics and patients from the marketing authorisation holders of Avtozma® (Celltrion Healthcare Ireland Limited) and Tyenne® (Fresenius Kabi Ireland). This includes information on the biosimilar medicine, training on correct injection and the administration technique and provision of a sharps management service. The relevant contact details are provided on the next page.

Celltrion Healthcare Ireland Limited (Avtozma®)

In order to avail of the patient support services for patients who have been prescribed **Avtozma®**, please use the Hibernian Healthcare at Home online portal https://schedule.hahirl.com/.

If you have not registered on the Hibernian Healthcare at Home online portal previously, please contact Hibernian Healthcare at Home at 01 460 4792 or by email at info@hibernianhealth.com, and access and support will be provided.

In order to obtain training pens and patient support materials for use in clinics, please contact

- Email: Enquiry_IE@celltrionhc.com
- Phone: 01 223 4026.

Fresenius Kabi Ireland (Tyenne®)

In order to avail of the patient support services for patients who have been prescribed **Tyenne®**, please use the Hibernian Healthcare at Home online portal https://schedule.hahirl.com/.

If you have not registered on the Hibernian Healthcare at Home online portal previously, please contact Hibernian Healthcare at Home at 01 460 4792 or by email at info@hibernianhealth.com, and access and support will be provided.

In order to obtain training pens and patient support materials for use in clinics, please contact

- Email: stuart.mackenzie-smith@fresenius-kabi.com
- Phone: (087) 353 2622.

Further information on the supports that are available can be found in the following document in the section entitled *Tocilizumab* under *Best-value medicines* on the MMP website www.hse.ie/mmp:

- BVB Medicine Patient and Clinic Support Services Tocilizumab

References:

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3. European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. 19 September 2022. Last updated 26/04/2023. Accessed at. https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf on 23/06/2026.
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5. Department of Health, Department of Public Expenditure, Infrastructure, Public Service Reform and Digitalisation, Health Service Executive, Medicines for Ireland. Framework Agreement on the Supply and Pricing of Medicines (FASPM) 2026 – 2029; The Irish Pharmaceutical Healthcare Association (IPHA). 3 March 2026. Accessed at https://healthservice.hse.ie/staff/information-healthcare-workers/pcrs/corporate-pharmaceutical-unit/ on 23/06/2026.
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7. HSE-Medicines Management Programme. MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting. November 2024. On file.