



Updates on recent initiatives from the HSE- Medicines Management Programme (MMP)

Dr. Claire Gorry, Chief I Pharmacist & Bernard Duggan, Chief I Pharmacist



Medicines Management
Programme

11th February 2026



Conflicts of Interest

MMP Team Members have no conflicts of interest to disclose.



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Contents

- Introduction to the HSE-Medicines Management Programme
- Health technology management initiatives
 - Managed Access Protocols
 - Best-value biological medicines





HSE-Medicines Management Programme

The HSE-MMP was established in January 2013

Aim - Sustained National Leadership relating to:

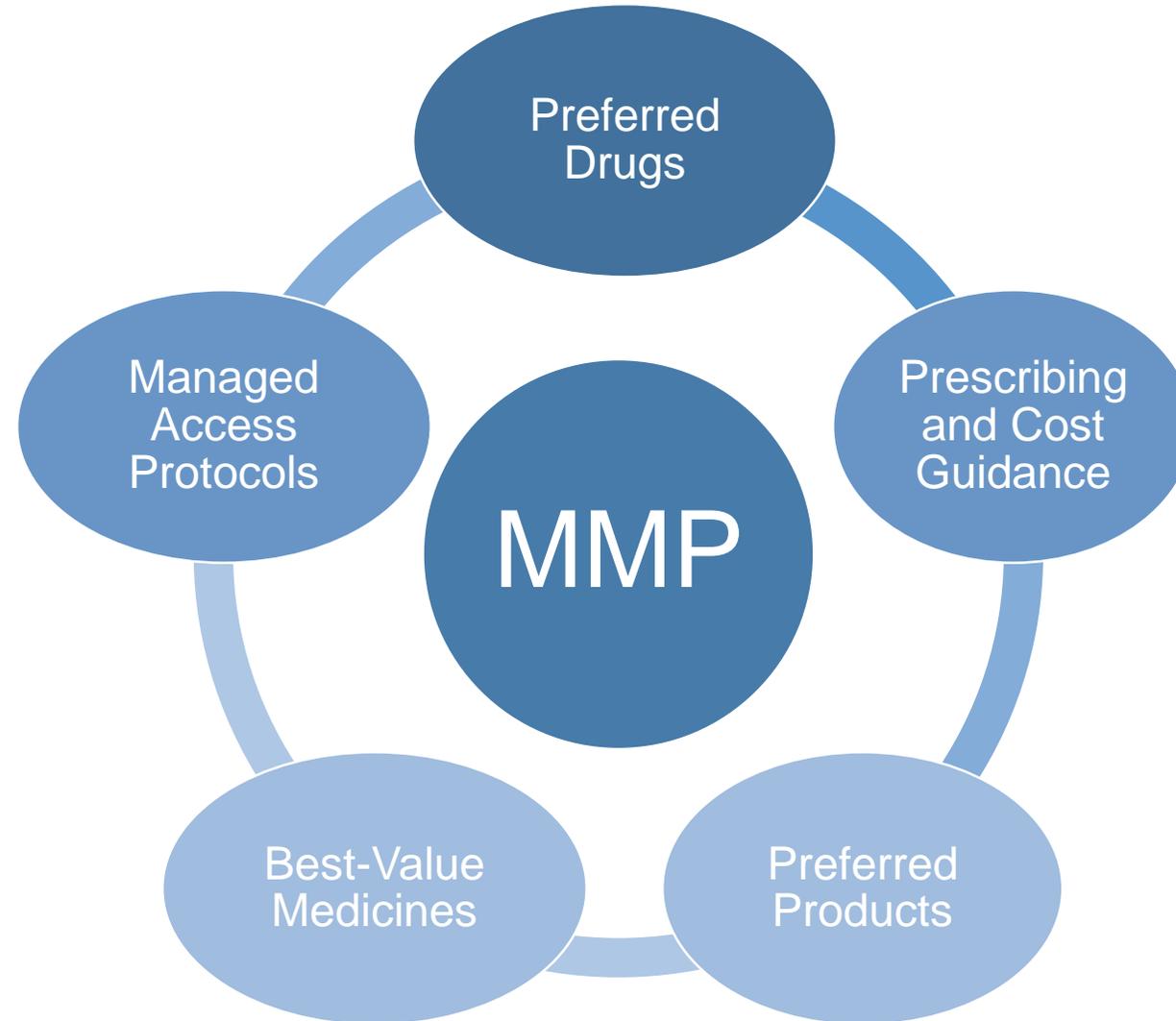
- ✓ **Safe**
- ✓ **Effective**
- ✓ **Cost-effective prescribing**



Medicines Management
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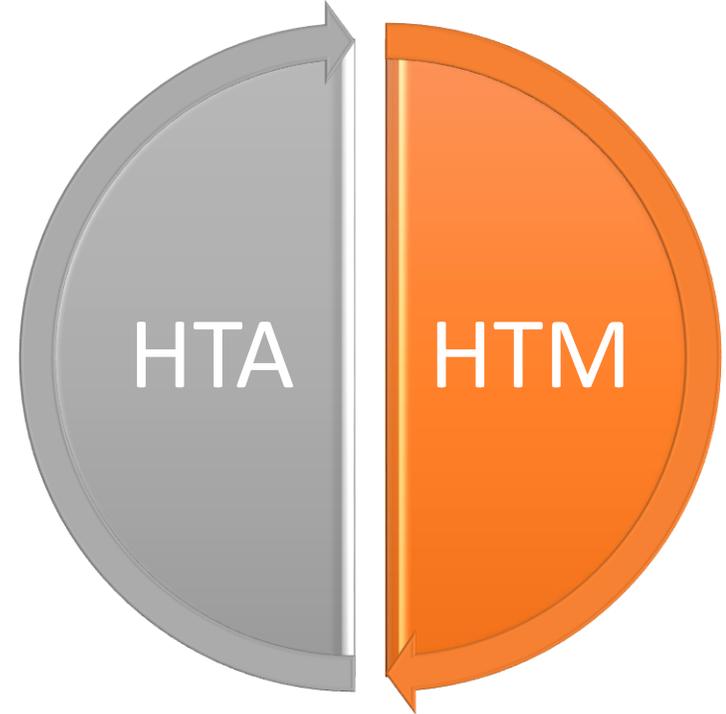
HSE-Medicines Management Programme





Health Technology Management

Measures to enhance the safe, effective and cost-effective use of medicines thereby controlling utilisation and expenditure



Medicines Management Programme

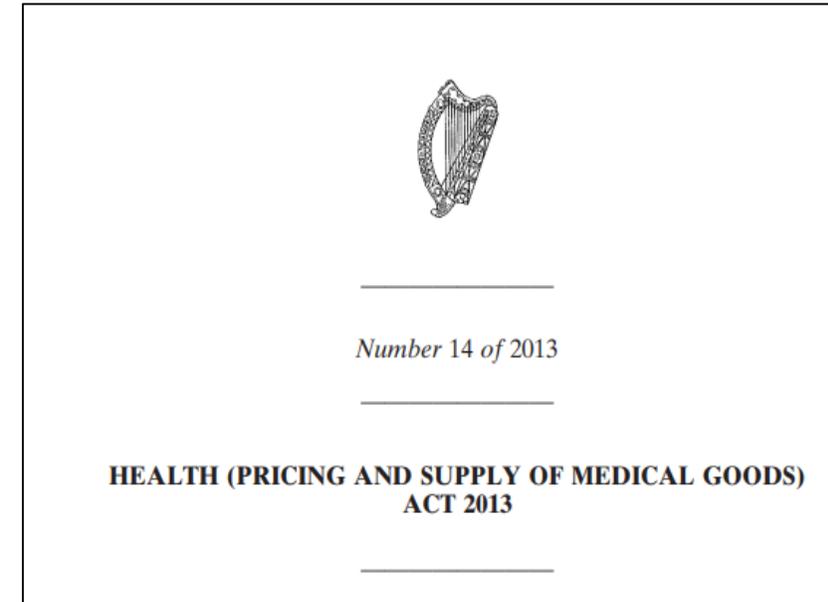


Health Act 2013

Part 4 (20):

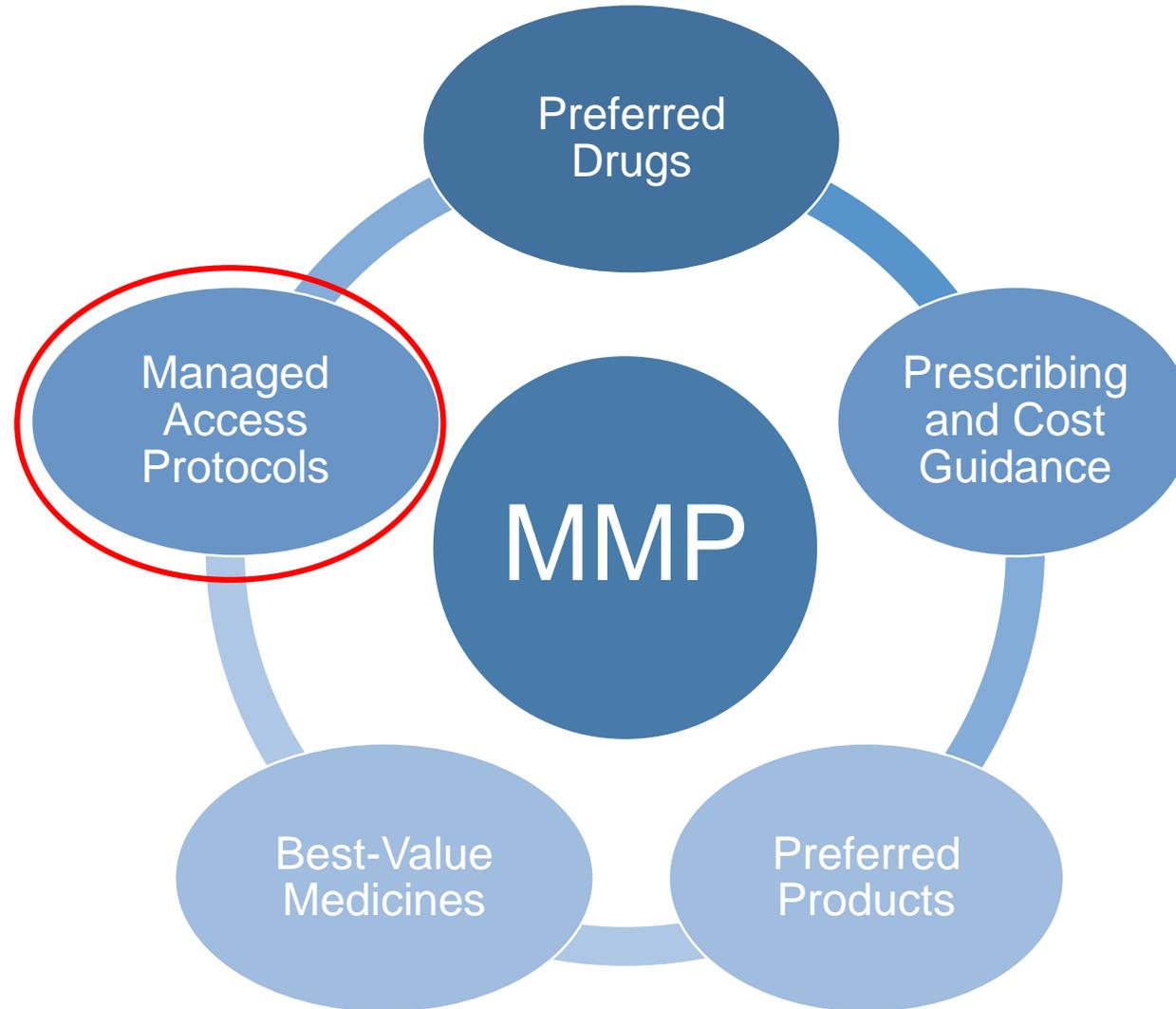
Executive may attach conditions to the supply of listed items in the interests of one or more of the following:

- a) Patient safety;
- b) Cost-effectiveness;
- c) Maximising appropriate use of listed items;
- d) Appropriately applying the resources available to the Executive.





HSE-Medicines Management Programme

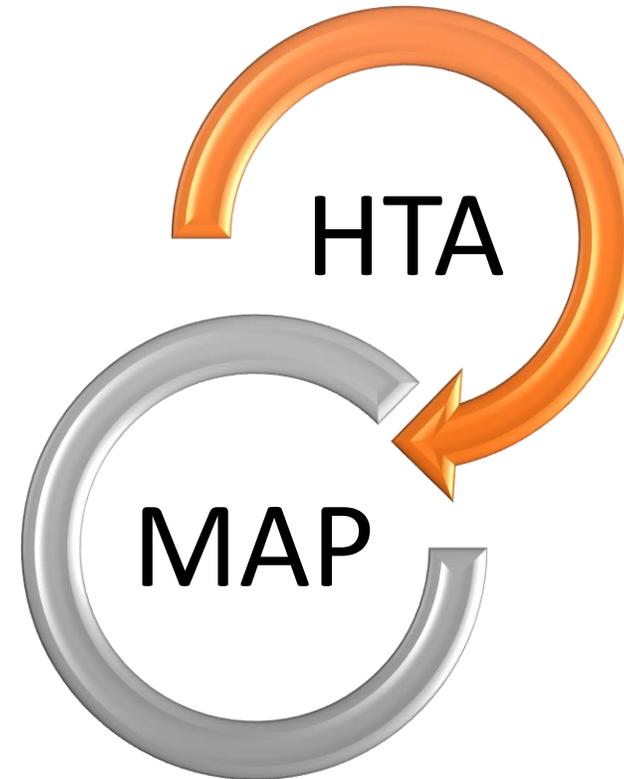




What is a Managed Access Protocol (MAP)?

A list of eligibility criteria attached to reimbursement support for a medicine

- ✓ Ensure reimbursement occurs only where a treatment is cost-effective
- ✓ Manage uncertainty in clinical effectiveness evidence
- ✓ Facilitate outcomes based reimbursement models
- ✓ Provide a measure of oversight, cost certainty and cost containment



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Managed Access Protocols

Components

- Prescriber controls
- Clinical diagnostic criteria
- Clinical severity criteria
- Previous lines of treatment
- Concomitant treatments
- Outcome data
- Automated controls of maximum reimbursement quantities, reimbursement duration



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Managed Access Protocols

- [Atopic Dermatitis](#)
- [Bempedoic Acid](#)
- [Berotralstat \(Orladeyo®\)](#)
- [Bulevirtide \(Hepcludex®\)](#)
- [Eculizumab](#)
- [Entrectinib \(Rozlytrek®\) - Lung Cancer](#)
- [Entrectinib \(Rozlytrek®\) - NTRK gene fusion](#)
- [Fostemsavir \(Rukobia®\)](#)
- [Inotersen \(Tegsedi®\)](#)
- [Lanadelumab \(Takhzyro®\)](#)
- [Larotrectinib \(Vitrakvi®\)](#)
- [Lidocaine \(Versatis®\)](#)
- [Liraglutide \(Saxenda®\)](#)
- [Migraine](#)
- [Nusinersen \(Spinraza®\)](#)
- [Odevixibat \(Bylvay®\)](#)
- [Onasemnogene abeparvovec \(Zolgensma®\)](#)
- [Patisiran \(Onpattro®\)](#)
- [PCSK9 Inhibitors](#)
- [Prurigo Nodularis - Dupilumab \(Dupixent®\)](#)
- [Risdiplam \(Evrysdi®\)](#)
- [Rivaroxaban 2.5mg](#)
- [Romosozumab \(Evenity®\)](#)
- [Sacubitril & Valsartan-\(Entresto®\)](#)
- [Severe Asthma - Dupilumab \(Dupixent®\)](#)
- [Tafamidis \(Vyndaqel®\)](#)
- [Teduglutide \(Revestive®\)](#)
- [THC/CBD \(Sativex®\)](#)
- [Tolvaptan \(Jinarc®\)](#)
- [Voretigene neparvovec \(Luxturna®\)](#)
- [Vutrisiran \(Amvuttra®\)](#)

www.hse.ie/mmp





Managed Access Protocols

Examples of MAPs introduced & updated (2025)

- Bulevirtide (Hepcludex[®])
- Iptacopan (Fabhalta[®]) for PNH
- Acoramidis (Beyonttra[®]) for ATTR-cardiomyopathy
- Updates to the MAP for high tech medicines for the treatment of atopic dermatitis
- Dupilumab (Dupixent[®]) for prurigo nodularis
- Medicines for severe asthma



Medicines for the management of severe asthma

With effect from 1 December 2025:

- Reimbursement of dupilumab, tezepelumab, benralizumab, and mepolizumab on the High Tech Arrangement, and reslizumab under Hospital Pricing Approval, is supported only for patients with severe refractory asthma who meet the criteria outlined in the MAP.



Medicines Management Programme

Managed Access Protocol – Medicines for the treatment of severe asthma

Medicine	Date of addition to Managed Access Protocol
Dupilumab (Dupixent [®])	01/11/2023
Benralizumab (Fasenra [®])	01/12/2025
Mepolizumab (Nucala [®])	01/12/2025
Reslizumab (Cinqaero [®])	01/12/2025
Tezepelumab (Tezspire [®])	01/12/2025

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved	Version 1.0	26/10/2023
Date updated	Version 1.1	03/11/2023
	Version 2.0	01/12/2025



Medicines for the management of episodic and chronic migraine

Reimbursement of atogepant, erenumab, fremanezumab, galcanezumab and rimegepant on the High Tech Arrangement, and eptinezumab under Hospital Pricing Approval, is supported only for the following subgroups of the licensed population, who meet the criteria outlined in this MAP:

- prophylaxis of episodic migraine in adults who have experienced treatment failure with three or more prophylactic treatments (atogepant, rimegepant)
- prophylaxis of chronic migraine in adults who have experienced treatment failure with three or more prophylactic treatments (atogepant, eptinezumab, erenumab, fremanezumab, galcanezumab).



Medicines Management Programme

Managed Access Protocol – Medicines for the management of episodic and chronic migraine

Medicine	Date of addition to Managed Access Protocol
Erenumab (Aimovig®)	01/09/2021
Fremanezumab (Ajovy®)	01/10/2021
Galcanezumab (Emgality®)	01/04/2022
Eptinezumab (Vyepti®)	28/06/2023
Atogepant (Aquipta®)	01/02/2025
Rimegepant (Vydura®)	01/02/2025

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved	Version 1.0	11/08/2021
Date updated	Version 1.1	01/09/2021
	Version 1.2	05/10/2021
	Version 1.3	01/04/2022
	Version 1.4	28/07/2023
	Version 2.0	31/01/2025



Medicines for the management of episodic and chronic migraine

Reimbursement is not supported for:

- rimegepant for the acute treatment of migraine,
- eptinezumab, erenumab, fremanezumab or galcanezumab for the prophylaxis of episodic migraine,
- concomitant use of any of the medicines reimbursed under this MAP.



Medicines Management Programme

Managed Access Protocol – Medicines for the management of episodic and chronic migraine

Medicine	Date of addition to Managed Access Protocol
Erenumab (Aimovig®)	01/09/2021
Fremanezumab (Ajovy®)	01/10/2021
Galcanezumab (Emgality®)	01/04/2022
Eptinezumab (Vyepti®)	28/06/2023
Atogepant (Aquipta®)	01/02/2025
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	Version 1.2	05/10/2021
	Version 1.3	01/04/2022
	Version 1.4	28/07/2023
	Version 2.0	31/01/2025



Bempedoic Acid

First-in-class adenosine triphosphate citrate lyase (ACL) inhibitor

- Lowers low-density lipoprotein cholesterol (LDL-C) by inhibition of cholesterol synthesis in the liver.

HSE reimbursement is supported for a subpopulation of the licensed indication, subject to a managed access protocol.



Medicines Management Programme

Managed Access Protocol –

Bempedoic Acid 180 mg film-coated tablets (Nilemdo®)

&

Bempedoic Acid 180 mg + Ezetimibe 10 mg film-coated tablets (Nustendi®)

Medicine	Date of addition to Managed Access Protocol
Bempedoic acid (Nilemdo®)	01/09/2024
Bempedoic acid + ezetimibe (Nustendi®)	01/09/2024

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved:	Version 1.0	27/08/2024



Liraglutide (Saxenda®) for adolescents

Submission of applications and prescriptions

- Applications for reimbursement approval of liraglutide for adolescents, will only be considered from consultants with specialist registration with the Irish Medical Council in a specialism relevant to obesity management in adolescent patients (e.g. endocrinology, paediatrics).
- Consultants must have access to a multi-disciplinary team (MDT) as part of Child and Adolescent Obesity Services to deliver lifestyle interventions for patients, and have agreed to the terms of this MAP and been approved by the HSE ('approved consultants').

Medicines Management Programme
Managed Access Protocol – Liraglutide (Saxenda®) for weight management in adolescents

Medicine	Date of addition to Managed Access Protocol
Liraglutide (Saxenda®)	01/02/2026

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved	Version 1.0	27/01/2026



Liraglutide (Saxenda®) for adolescents

Phase 1 - Initiation:

- Age 12 – 17 years
- BMI \geq 99.6th percentile
- Confirmation of:
 - Participation in lifestyle interventions delivered by an MDT as part of Child and Adolescent Obesity Services.
 - At least two of the following comorbidities relating to obesity:
 - Uncontrolled metabolic complications
 - Biomechanical complications requiring treatment or limited mobility
 - Shortness of breath
 - Significant psychosocial complications or concerns
 - Sleep disordered breathing

Phase 2 - Continuation:

- Continuation of lifestyle interventions delivered by an MDT as part of Child and Adolescent Obesity Services.
- Response to treatment – defined as at least a 4% reduction in initial BMI after 12 weeks at 3 mg/day or maximum tolerated dose.



Saxenda®

Liraglutide (Saxenda®) for weight management in adolescents: Managed Access Protocol published and implemented Feb 2026

Liraglutide (Saxenda) for weight management in adults: Managed Access Protocol published and implemented Jan 2023

Mounjaro® & Wegovy®

Tirzepatide (Mounjaro®)

- For weight management in adults: HTA complete
- For type 2 diabetes mellitus in adults: HTA complete

Semaglutide (Wegovy®)

- For weight management in adults: NCPE awaiting submission of HTA
- For weight management in adolescents: A full HTA is not recommended. The NCPE recommends that semaglutide not be considered for reimbursement at the submitted price



A Managed Access Protocol for Liraglutide for Weight Management: A Retrospective, Observational Study in Ireland

Rosealeen Barrett, MPharm, Amelia Smith, PhD, Claire Gorry, PhD, Stephen Doran, MSc, Michael Barry, MD, Laura McCullagh, PhD

ABSTRACT

Objectives: Pivotal trial data highlight that liraglutide (Saxenda) is effective for weight management, versus placebo. However, cost-effectiveness in Ireland, is not proven. Here, we demonstrate how a Managed Access Protocol (MAP) in Ireland's healthcare service facilitates access to this high-budget-impact drug in a real-world subpopulation (of the fully licensed population), in whom the intervention is expected to be the most cost-effective, as determined by health technology assessment, while containing overall expenditure.

Methods: Two key data sources were analyzed; (1) national anonymized MAP database of liraglutide applications and (2) national reimbursed pharmacy claims database. Key characteristics of the applications approved for reimbursement under the MAP were compared with (1) those of an identified pivotal trial subgroup and (2) those not approved for reimbursement under the MAP. Utilization and expenditure were compared with those predicted in the absence of the MAP.

Results: Of the 7927 applications submitted in the first year of the MAP by physicians for individual patients, 52.2% were approved. Differences were noted in most of the key characteristics (including mean age, mean HbA1c, and mean body mass index) in the groups compared. Expenditure on liraglutide was approximately €3.1 million in 2023. Had all applications submitted under the MAP had been approved, expenditure of up to €5.5 million would have been expected.

Conclusions: The MAP facilitates access for a subpopulation in whom liraglutide is effective and also expected to be most cost-effective, according to health technology assessment.

Keywords: cost-effective prescribing, drug reimbursement, health technology management, Managed Access Protocol.

VALUE HEALTH. 2025; ■(■):■-■

Highlights

- Health technology management initiatives, such as Managed Access Protocols (MAPs), are increasingly becoming a feature of the reimbursement landscape in Ireland.
- The liraglutide (Saxenda) MAP facilitates access for a key subpopulation of interest while containing health-payer costs.
- Implementing MAPs across other therapeutic areas may balance affordability of novel, high-cost drugs with appropriate patient access.

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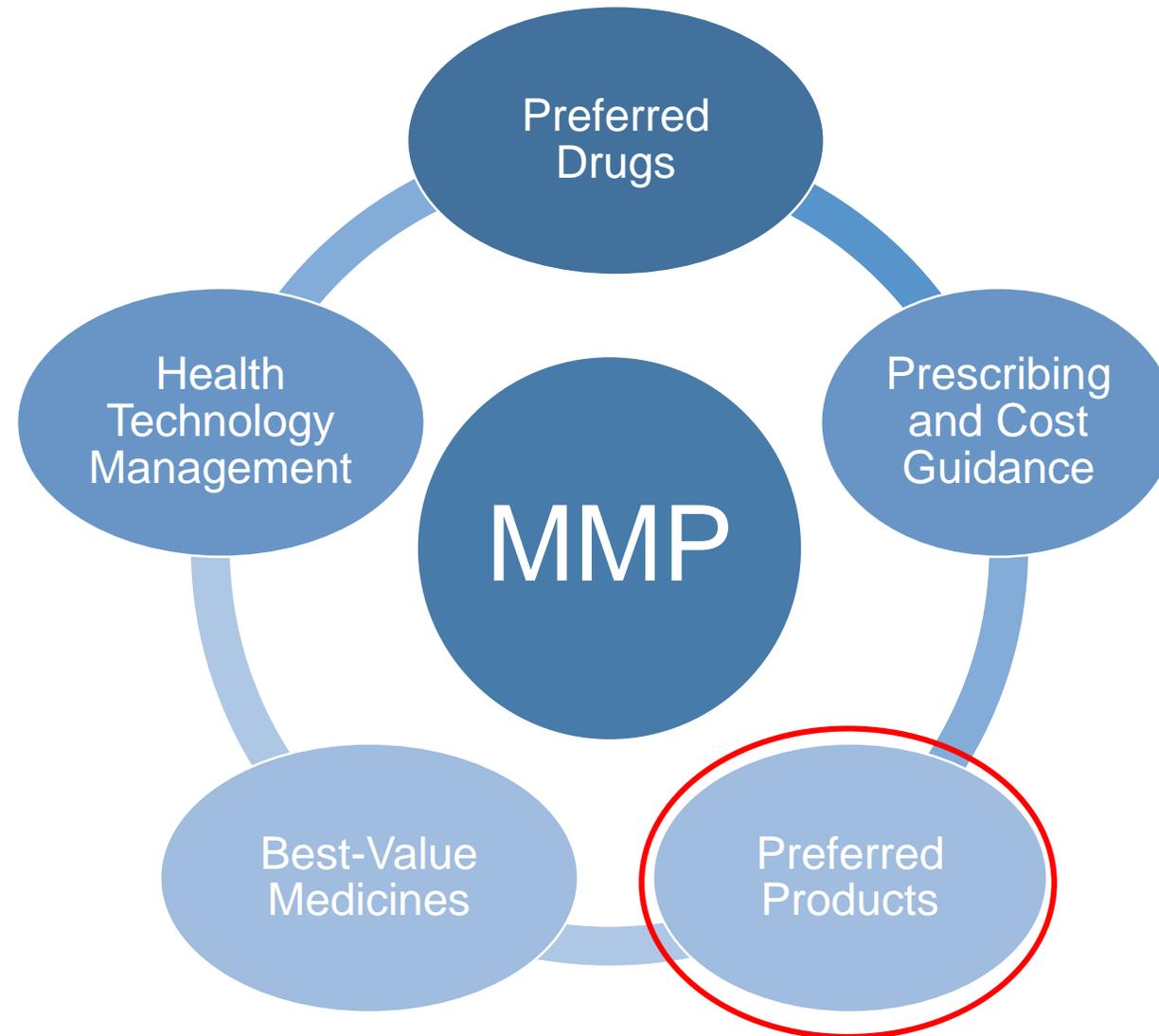
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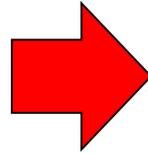
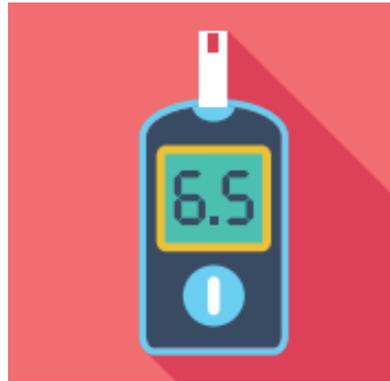
HSE-Medicines Management Programme





Glucose monitoring

Glucose monitoring has long been an accepted part of diabetes management, recent years have seen rapid developments in the available technologies for glucose monitoring, with associated increases in costs.





Preferred CGM Sensors

The MMP has identified two preferred CGM sensors (List A) with associated systems, for people with diabetes requiring CGM who are not insulin pump users.

Preferred CGM sensors – List A		
CGM sensor	Reimbursement code	Pack size
Freestyle Libre 2	85581	1
Dexcom ONE+	97636	1





Preferred CGM Sensors Recommendation

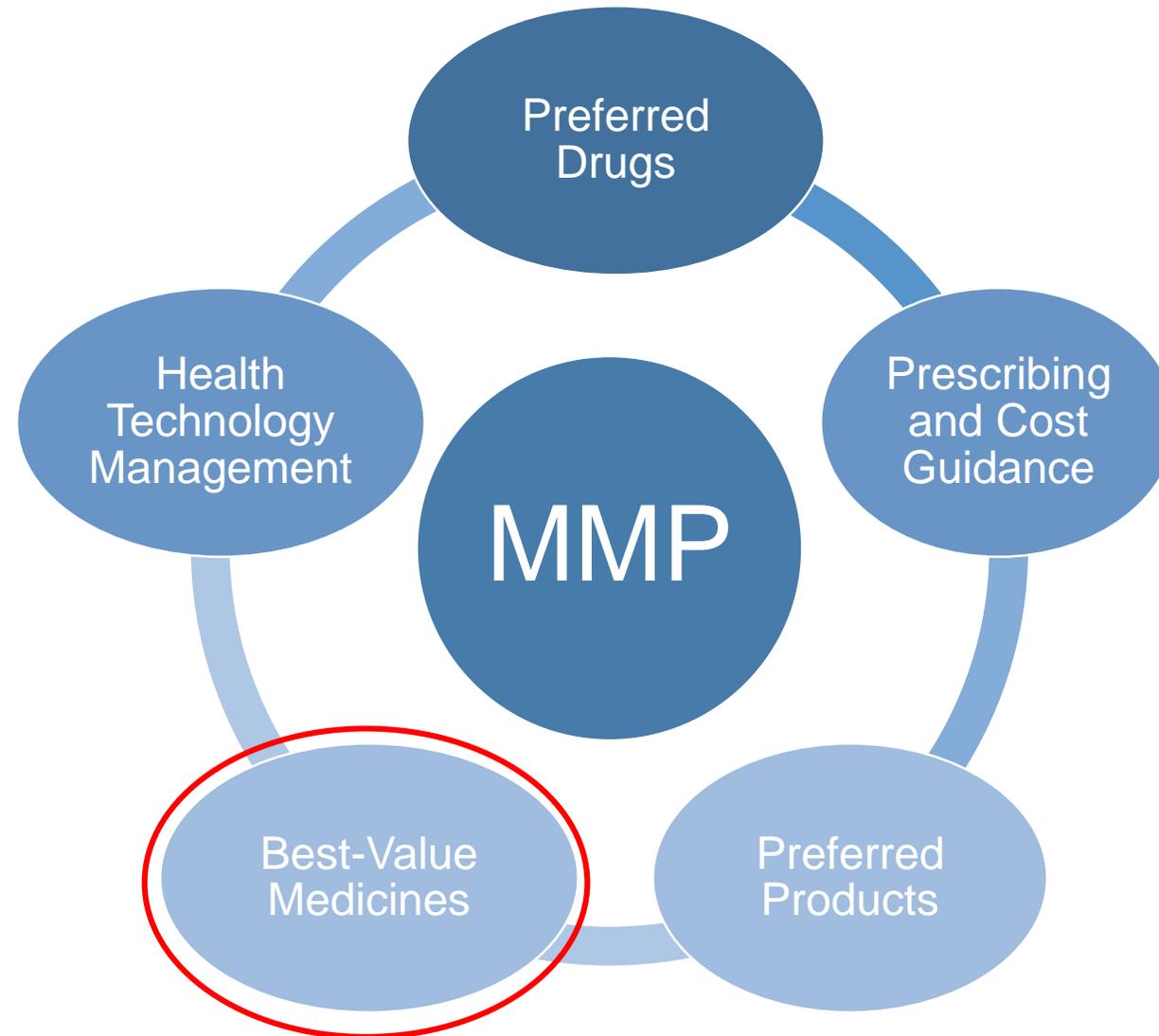
The MMP recommends a preferred CGM sensor with associated system from List A for people with diabetes requiring CGM who are not insulin pump users, when:

- First initiating CGM
- Continuing CGM upon review
- Changing CGM sensor with associated system





HSE-Medicines Management Programme





Best-Value Biological Medicines / Best-Value Medicines

What are biosimilar medicines?



Biological and biosimilar medicines come from living cells

Biosimilar medicines are **highly similar**

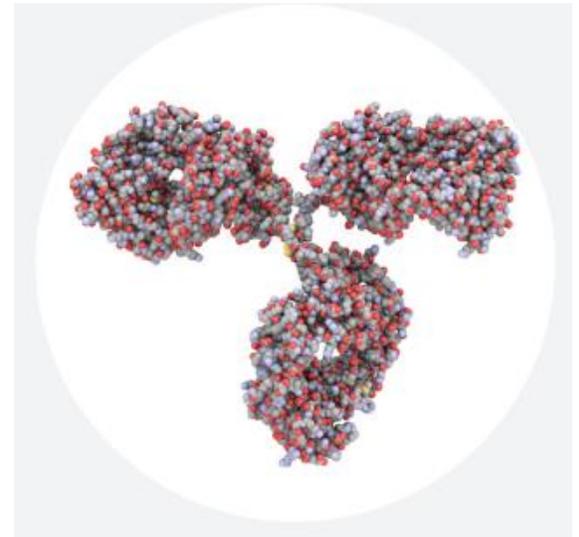
The effects are the same



Biological Medicines – What are they?

A **biological medicine** is a medicinal product, the active substance of which is produced by or extracted from a biological source (a **biological substance**)

- Tailor made to fit the desired target
- **Large molecules**
- Rather than been synthesised by chemical methods, biological medicines are **made from cell cultures of living organisms**
- Proteins





High Tech Arrangement 2023: Top 20 Expenditure

Medicine	Total expenditure	Medicine	Total expenditure
1. Adalimumab	€129.7 million	11. Tocilizumab	€19.6 million
2. Ustekinumab	€67.3 million	12. Pomalidomide	€19.3 million
3. Ivacaftor, Tezacaftor and Elexacaftor	€39.3 million	13. Enzalutamide	€17.9 million
4. Etanercept	€36.3 million	14. Guselkumab	€17.1 million
5. Ivacaftor	€34.6 million	15. Nintedanib	€16.1 million
6. Secukinumab	€33.1 million	16. Abiraterone	€14.4 million
7. Ibrutinib	€22.9 million	17. Palbociclib	€14.1 million
8. Fingolimod	€22.7 million	18. Pegfilgrastim	€13.1 million
9. Golimumab	€20.3 million	19. Ruxolitinib	€13.0 million
10. Lenalidomide	€20.2 million	20. Gonadotropins, Combinations	€12.0 million





High Tech Arrangement 2023: Top 20 Expenditure

Medicine	Total expenditure	Medicine	Total expenditure
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2. Ustekinumab	€67.3 million		
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6. Secukinumab	€33.1 million		
		18. Pegfilgrastim	€13.1 million
9. Golimumab	€20.3 million		
		20. Gonadotropins, Combinations	€12.0 million





High Tech Arrangement 2023: Top 20 Expenditure

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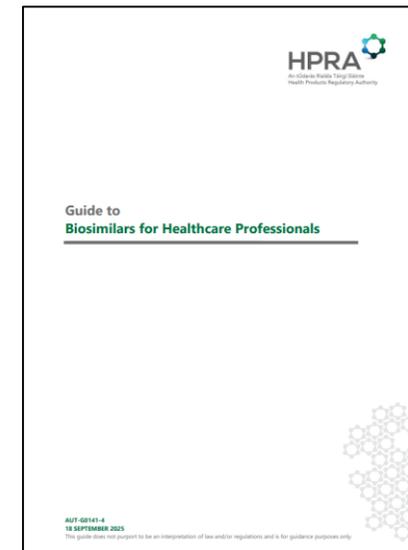
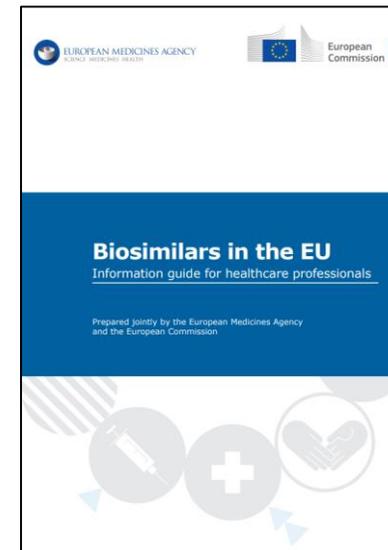




What is a Biosimilar Medicine?

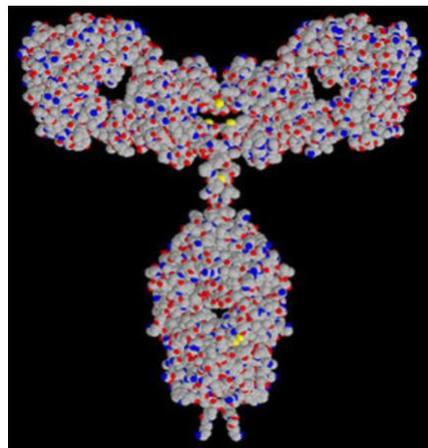
A **biosimilar medicine** is a medicine highly similar to another biological medicine already marketed in the EU ('reference medicine')

- Type of biological medicine
- Highly similar to the reference medicine
- No clinically meaningful differences compared with reference medicine
- Variability of biosimilar medicine kept within strict limits
- Same strict standards of quality, safety and efficacy

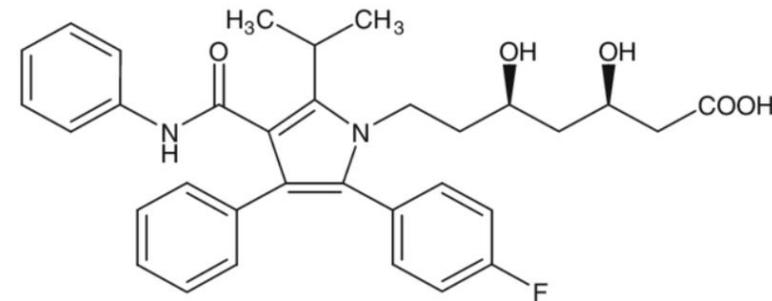


HE Biosimilar Medicines Versus Generic Medicines?

- Generic medicines have the same qualitative and quantitative composition as the originator medicine (i.e. an exact copy)
 - Development based on demonstration of bioequivalence
- Biosimilar medicines are similar but not identical versions of the reference biological medicine
 - Development based on demonstration of biosimilarity using comparability studies



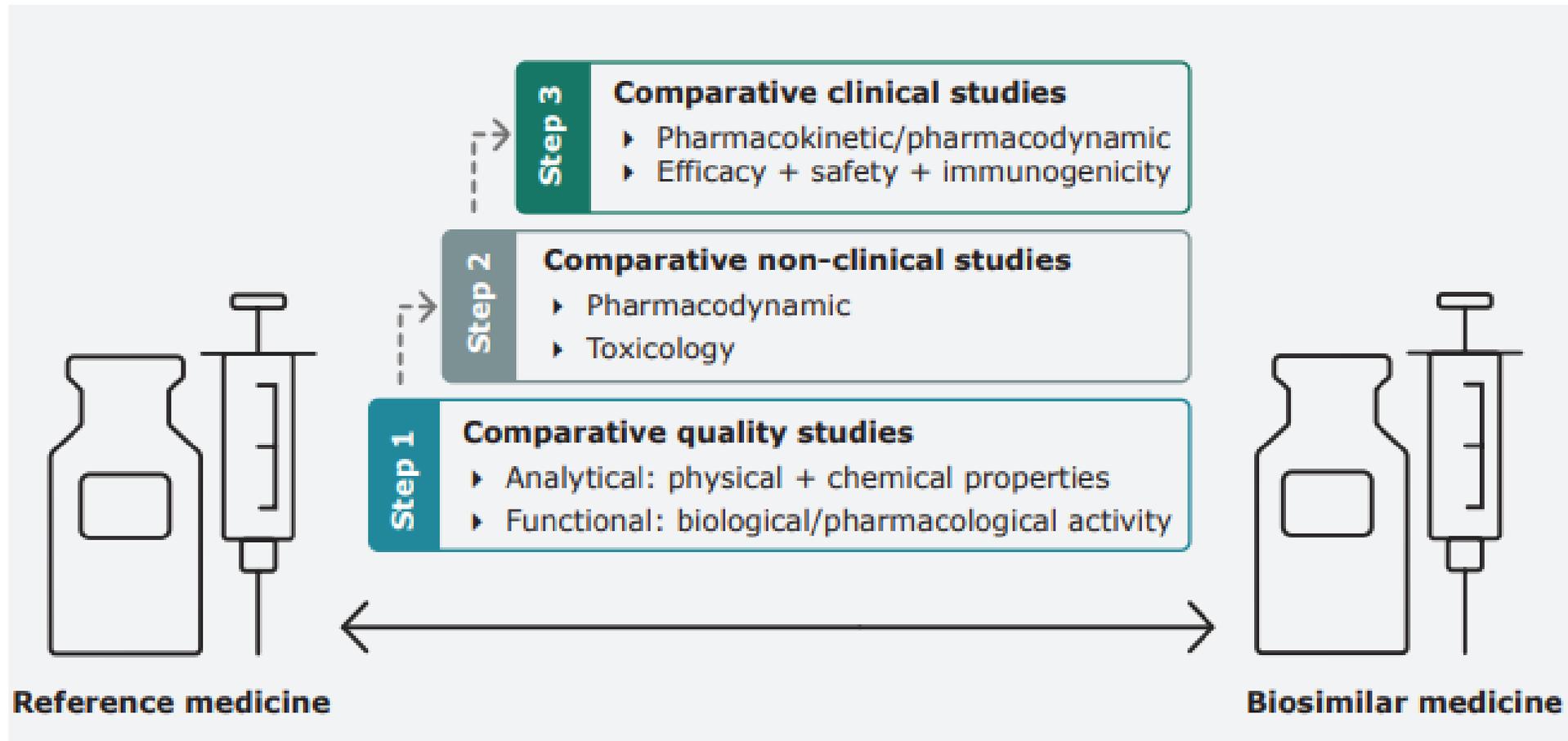
Adalimumab



Atorvastatin



Biosimilar Medicines





Interchangeability

Biosimilars are
interchangeable.

They can be used instead
of their reference medicine
or another biosimilar of the
same reference product.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



21 April 2023
EMA/627319/2022

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Joint EMA-HMA statement on interchangeability:

Biosimilars approved in the EU are interchangeable

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product. Interchange should only take place after careful consideration of the approved conditions of use (i.e., consulting the most recent product information).

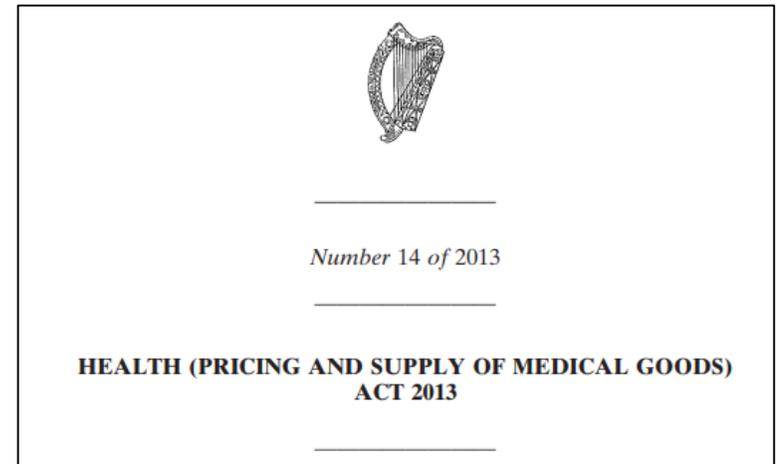
Decisions on how to implement interchangeability either through switching (under the control of the prescriber) and/or substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level), are not within the remit of EMA and are managed by individual member states.





Interchangeability

- Possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect
- Replacing a reference medicine with a biosimilar (or vice versa) or replacing one biosimilar with another of the same reference medicine:
 - **Switching**
 - **Automatic Substitution**





EMA New Medicine Recommendations 2025



104

POSITIVE
OPINIONS



7

NEGATIVE
OPINIONS



22

WITHDRAWN
APPLICATIONS³

Among the positive opinions:

38 New active substances

6 PRIME

16 Orphan medicines²

4 Advanced therapy medicinal product (ATMP)

41 Biosimilars

10 Generics

3 Accelerated assessments

8 Conditional marketing approvals

2 Approval under exceptional circumstances





EU-Authorised Biosimilar Medicines

- Adalimumab
- Aflibercept
- Bevacizumab
- Denosumab
- Eculizumab
- Enoxaparin sodium
- Epoetin alfa / zeta
- Etanercept
- Filgrastim
- Follitropin alfa
- Golimumab
- Infliximab
- Insulin aspart / glargine / lispro
- Natilizumab
- Pegfilgrastim
- Ranibizumab
- Somatropin
- Teriparatide
- Tocilizumab
- Trastuzumab
- Ustekinumab





EU-Authorised Biosimilar Medicines: HSE Reimbursement List

- **Adalimumab**
- Aflibercept
- Bevacizumab
- **Denosumab**
- Eculizumab
- Enoxaparin sodium
- Epoetin alfa / zeta
- **Etanercept**
- **Filgrastim**
- **Follitropin alfa**
- **Golimumab**
- **Infliximab**
- Insulin aspart / glargine / lispro
- Natilizumab
- **Pegfilgrastim**
- Ranibizumab
- Somatropin
- **Teriparatide**
- **Tocilizumab**
- Trastuzumab
- **Ustekinumab**





Best-Value Biological / Best-Value Medicine Process

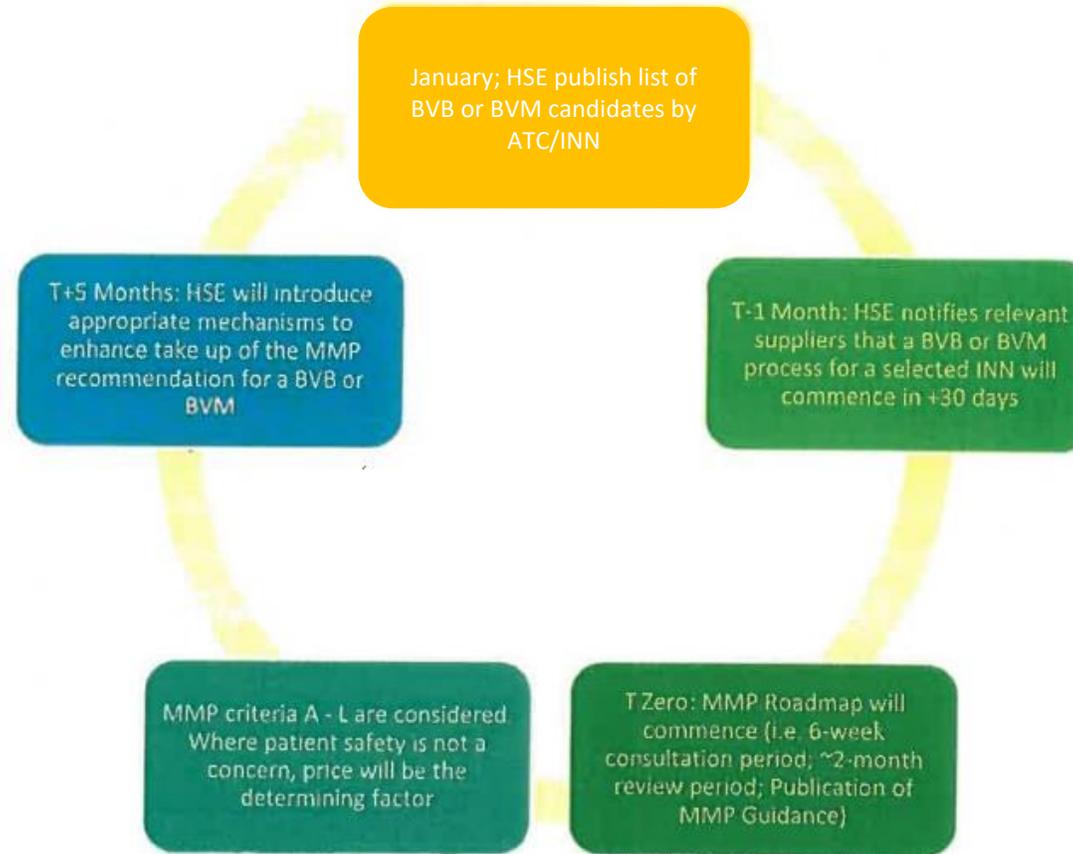
- Ensures that efficiencies presented by availability of biosimilar medicines are fully realised to achieve best value for the state
- Predominately focused on biological medicines on HSE Reimbursement List for which biosimilar medicines are available
 - Adalimumab
 - Etanercept
 - Filgrastim
 - Glatiramer
 - Long-acting G-CSFs
 - Teriparatide
 - Tocilizumab
 - Ustekinumab



Best-Value Biological / Best-Value Medicine Process

FRAMEWORK
AGREEMENT ON THE
SUPPLY AND PRICING
OF MEDICINES

FRAMEWORK
AGREEMENT ON THE
SUPPLY AND PRICING
OF GENERIC,
BIOSIMILAR, AND
HYBRID MEDICINES



T = time point, e.g., T minus 1 is one month before a key point; T Zero is a key point; T+5 Months is 5 months after T Zero



Best-value medicines

The Medicines Management Programme has identified best-value medicines in the following areas:

- [Best-value biological medicines: adalimumab + etanercept](#)
- [Filgrastim](#)
- [Glatiramer acetate](#)
- [Long-acting granulocyte-colony stimulating factors](#)
- [Teriparatide](#)

BVB/BVM Processes 2025

Information in relation to potential best-value biological (BVB) medicine and best-value medicine (BVM) processes for 2025.

[MMP BVB and BVM Processes 2025 \(PDF, size 454.5 KB, 1 page\)](#)



Medicines Management Programme

Best-value biological medicine: Filgrastim on the High Tech Arrangement

Approved by	Professor Michael Barry, Clinical Lead, MMP	
Date approved:	Version 1.0	05/03/2025

www.hse.ie/mmp

Best-value biological medicines: Filgrastim

The Medicines Management Programme has identified best-value biological (BVB) medicines for medicinal products containing filgrastim on the High Tech Arrangement.

The MMP recommends the following as BVB medicines for filgrastim on the High Tech Arrangement:

- Accofil® (Accord Healthcare Ireland Limited)
- Tevagrastim® (Teva Pharmaceuticals Ireland).

A copy of the MMP Evaluation Report is available in the Related Files section below.

Related Files



[MMP Evaluation Report BVB Medicines - Filgrastim](#)

Format:PDF | File Size:959KB



BVB Tocilizumab

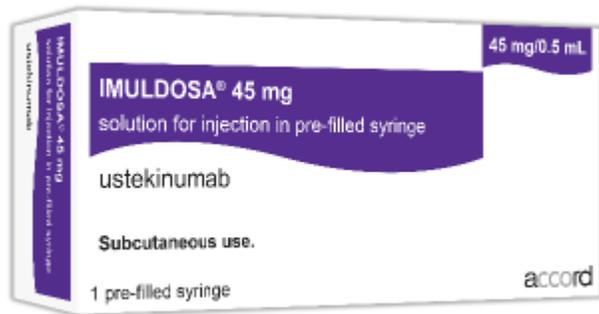
- BVB Medicine Process completed November 2025
- Reference Medicine – RoActemra®
- Biosimilar Medicines –Tyenne® (Avtozma®, Tocilizumab Stada [Tofidence®])
- MMP recommends Tyenne® as the BVB medicine for tocilizumab on the High Tech Arrangement
- New + established patients





BVB Ustekinumab

- BVB Medicine Process completed November 2025
- Reference Medicine – Stelara®
- Biosimilar Medicines – Imuldosa®, Otulfi®, Pyzchiva®, Steqeyma®, Wezenla®, Uzpruvo®
- BVB Medicines:



Imuldosa®



Otulfi®



Pyzchiva®



Wezenla®



BVB Ustekinumab

- 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.



BVB Medicines - Implementation

- Resources for healthcare professionals

Best-value biological medicines

The Medicines Management Programme has identified best-value biological (BVB) medicines for TNF- α inhibitors under the High Tech Arrangement.

The MMP recommends the following BVB medicines for adalimumab and etanercept:

- Adalimumab:
 - Citrate-containing: **Hyrimoz, Idacio, Imraldi**
 - Citrate-free: **Amgevita, Hulio, Yuflyma**
- Etanercept: **Benepali, Erelzi**

Clinicians should give due consideration to the prescription of these agents when prescribing a TNF- α inhibitor. Implementation of the BVB medicines will lead to significant savings for the health service, in the order of millions of euros.

The MMP recommends Amgevita as the BVB medicine for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the High Tech Arrangement. This presentation of adalimumab is predominately used in paediatric patients. The MMP wrote a letter to prescribers in relation to this in May 2021.

Resources to support prescribing of the BVB medicines are located in the Related Files section below:

- Questions and Answers for Healthcare Professionals.
- MMP Product Information Sheets for Amgevita, Benepali, Erelzi, Hulio, Hyrimoz, Idacio, Imraldi and Yuflyma
- Contact information for MMP support.
- Contact information for patient support services for Amgevita, Benepali, Erelzi, Hulio, Hyrimoz, Idacio, Imraldi and Yuflyma
- Templates for switching letters for Amgevita, Benepali, Erelzi, Hulio, Hyrimoz, Idacio, Imraldi and Yuflyma.

From 1 February 2020, it is HSE policy that all adult patients who are commencing treatment with adalimumab or etanercept should be prescribed a best-value biological (BVB) medicine. Further information in relation to this can be found [here](#).

The MMP wrote a letter to prescribers updating them on the BVB medicine initiative in January 2021.

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BVB Medicines - Implementation

- Resources for healthcare professionals





BVB Medicines - Implementation

- Resources for healthcare professionals
- High Tech Hub
- Engagement with National Clinical Programmes
- Engagement with patient support groups
- Information sessions
- Gain share arrangement
- Policy for new patients
- Regular communications with prescribers



BVB Medicine Processes 2026

- Eculizumab
- Denosumab
- Golimumab



Acknowledgements

HSE-Medicines Management Programme

HSE-Primary Care Reimbursement Service

Thank you for listening!

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