Medicines Management Programme

Best-Value Biological Medicines:

Review of submission for Yuflyma® 20 mg

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BVB	Best-Value Biological
CPU	Corporate Pharmaceutical Unit
EMA	European Medicines Agency
EPAR	European Public Assessment Report
EU	European Union
Ex	Excluding
HMA	Heads of Medicines' Agencies
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
Inc	Including
INN	International non-proprietary name
JA	Juvenile idiopathic arthritis
mg	Milligrams
ml	Millilitres
MMP	Medicines Management Programme
PCRS	Primary Care Reimbursement Service
PFP	Pre-filled pen
PFS	Pre-filled syringe
PIL	Patient information leaflet
SmPC	Summary of Product Characteristic
TNF-α	Tumour necrosis factor-alpha
VAT	Value-added tax

1. Executive Summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) supports the safe, effective and cost-effective use of biological medicines including biosimilar medicines (or 'biosimilars'). The MMP recognises the potential savings arising from the availability of biosimilars. These savings, however, can only be realised by increased utilisation of best-value biological (BVB) medicines, including biosimilars.

The MMP has previously undertaken a review of biological medicines containing adalimumab that are on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement. Arising from this, BVB medicines have been identified for presentations of adalimumab 40 milligrams (mg) and 80 mg solution for injection that are available in self-administered injection devices, i.e. pre-filled pens (PFP) and pre-filled syringes (PFS).[1-9]

The MMP published a report on 31 March 2021 in which it recommended **Amgevita®** as the BVB medicine for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement.[10] On 23 October 2024, the MMP published a report in which it recommended that BVB status be assigned to the revised formulation of **Amgevita®** 20 mg.[8]

The MMP has reviewed a submission received from Celltrion Healthcare Ireland at the request of the Corporate Pharmaceutical Unit (CPU) of the HSE-Primary Care Reimbursement Service (PCRS). The MMP considers **Yuflyma®** 20 mg to be comparable to the MMP BVB medicine for adalimumab 20 mg. The MMP recommends that BVB medicine status be assigned to **Yuflyma®** 20 mg.

The MMP recommends Amgevita® and Yuflyma® as the best-value biological medicines for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement.

Clinicians should prescribe Amgevita® or Yuflyma® when issuing a prescription for adalimumab 20 mg solution for injection on the High Tech Arrangement.

Implementation of this recommendation will lead to savings for the health service.

2. Background

2.1 Best-Value Biological Medicines – Adalimumab

The MMP has previously undertaken reviews of biological medicines containing adalimumab 20 mg, 40 mg and 80 mg that are available on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement. Arising from this, BVB medicines have been identified for presentations of adalimumab 40 mg solution for injection that are available in self-administered injection devices, i.e. PFP and PFS:[1-5,7,8]

- Citrate-containing: Idacio®
- Citrate-free: Amgevita®, Hukyndra®, Hulio®, Humira®, Imraldi®, Yuflyma®.

A BVB medicine has also been identified for presentations of adalimumab 20 mg solution for injection that are available in a self-administered injection device, i.e. PFS:[8,10]

- Amgevita®.

BVB medicines have also been identified for presentations of adalimumab 80 mg solution for injection that are available in a self-administered injection device, i.e. PFP:[6,9]

- Amgevita®, Humira® and Yuflyma®.

2.2 Biosimilars

A biosimilar medicine for adalimumab 20 mg, Amgevita®, is available on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement, since November 2018.[11]

Celltrion Healthcare Ireland have submitted a formal pricing and reimbursement application to the HSE for addition of their biosimilar medicine containing adalimumab 20 mg solution for injection in a PFS, Yuflyma®, to the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement.

2.3 HSE-Primary Care Reimbursement Service Request

The CPU of the PCRS requested the MMP to review a submission for BVB medicine status from Celltrion Healthcare Ireland in relation to their biosimilar medicine containing adalimumab 20 mg, Yuflyma® 20 mg.

3. Scope

In line with the original BVB medicine evaluation process for adalimumab 20 mg (March 2021), the presentation of Yuflyma® for which Celltrion Healthcare Ireland have provided a submission is considered to be within scope of evaluation for BVB medicines status as it contains a 20 mg dose of adalimumab within a self-administered injection device.

4. Definitions

For the purposes of this document, the reimbursement price refers to the reimbursed price of the medicinal product as listed in the High Tech Drug File maintained by the PCRS. It may not represent the final acquisition cost to the HSE of the biological medicine, which may also include any rebates and commercial-in-confidence arrangements that are in place. Both the reimbursement price and the acquisition cost are exclusive of value-added tax (VAT). Costs are correct as of 31 March 2025.

Information contained in this evaluation report on Amgevita® 20 mg PFS, is reflective of the revised formulation of Amgevita® 20 mg PFS that was added to the HSE Reimbursement List on 1 November 2024, for prescribing and supply under the High Tech Arrangement.

5. Evaluation Process

The review of the submission received from Celltrion Healthcare Ireland was carried out in accordance with the evaluation process in the *MMP roadmap for the prescribing of best-value biological (BVB) medicines.*[12]

In line with the *MMP roadmap for the prescribing of best-value biological (BVB) medicines*, the MMP considered the following criteria when reviewing the BVB medicine submission received from Celltrion Healthcare Ireland:[12]

1. Acquisition cost
2. Therapeutic indications
3. Formulation considerations
4. Product range including pack sizes and strengths available
5. Product stability including storage requirements
6. Administration devices
7. Patient factors
8. Expenditure in the therapeutic area and potential for cost efficiencies

9. Clinical guidelines
10. Security of supply to the Irish Market
11. Utilisation and clinical experience with the biological medicine
12. Any other relevant factors with respect to the particular INN.

6. Evaluation

6.1 Acquisition Cost

The proposed reimbursement price of Yuflyma® 20 mg PFS is €243.04 per pack, as outlined in Table 1.

Table 1 Proposed reimbursement price of Yuflyma® 20 mg under the High Tech Arrangement[13]

Biological Medicine	Pack size	Reimbursement Price per pack
Yuflyma® 20 mg PFS	2	€243.04

mg: milligrams; PFS: Pre-filled syringe

Clause 8.2.2 of the Framework Agreement on the Supply and Pricing of Generic, Biosimilar and Hybrid Medicines (2021) states that the price that a supplier shall submit to the HSE of a new biosimilar medicine for which an application is made for its addition to the reimbursement list shall be no greater than 55% of the 1st of October 2021 price of the equivalent branded original medicine.[14] The proposed reimbursement price of Yuflyma® 20 mg PFS is in line with this requirement.

The submission received from Celltrion Healthcare Ireland included revised commercial terms for the biosimilar medicine listed above, resulting in a significant reduction in the acquisition cost to the HSE.

Recommendation

For the 20 mg dosage of adalimumab formulated as a PFS, the acquisition cost to the HSE for Yuflyma® 20 mg is in line with the acquisition cost of the BVB medicine for adalimumab currently recommended by the MMP.

6.2 Therapeutic indications

Table 2 summarises the licensed therapeutic indications of Yuflyma® 20 mg, and compares them to the licensed indications of the reference medicine, Humira®.

Table 2 Summary of licensed therapeutic indications for Humira® 20 mg and Yuflyma® 20 mg*

Brand (INN)	Juvenile idiopathic arthritis (JA) -Polyarticular JA -Enthesitis-related arthritis	Paediatric Plaque Psoriasis	Paediatric Crohn's disease	Paediatric uveitis
Humira® (Adalimumab)[15]	✓	✓	✓	✓
Yuflyma® (Adalimumab)[16]	✓	✓	✓	✓

INN: International non-proprietary name; JA: Juvenile idiopathic arthritis;
**Please refer to individual SmPC for full prescribing information.*

Recommendation
Overall, in relation to the criterion of therapeutic indications, the MMP is of the view that Yuflyma® 20 mg is equivalent to the reference medicine, Humira® 20 mg. Yuflyma® 20 mg is licensed for the all of the therapeutic indications that the MMP BVB medicine for adalimumab 20 mg is licensed for.

6.3 Formulation considerations

Yuflyma® 20 mg is formulated as a clear to slightly opalescent, colourless to pale brown solution for injection in a PFS. One PFS contains 20 mg of adalimumab in 0.2 mL solution, i.e. 100 mg/mL. Yuflyma® 20 mg PFS contains the following excipients; acetic acid, sodium acetate trihydrate, glycine, polysorbate 80 and water for injections.[16]

Yuflyma® 20 mg does not contain citrate in its formulation.[16]

Injection site reactions are reported in the section on undesirable effects in the Summary of Product Characteristics (SmPC) of the reference biological medicine Humira®; this states that in pivotal clinical trials in adults and children, 12.9% of patients treated with Humira® developed injection site reactions, compared to 7.2% of patients who received treatment with placebo or active control. The injection site reactions are described as erythema, itching, haemorrhage, pain or swelling. The SmPC also states that injection site reactions generally did not necessitate discontinuation of the medicinal product.[15]

The SmPC for Yuflyma® carries the same statement as Humira® in relation to injection site reactions.[16]

The formulation of Yuflyma® 20 mg is reflective of certain elements of the formulation of the BVB medicine for adalimumab 20 mg, i.e. it contains adalimumab at a concentration of 100 mg/mL and it does not contain citrate.

6.3.1 European Public Assessment Report - Yuflyma®

In the clinical safety section of the European Public Assessment Report (EPAR) for Yuflyma®, the incidence of injection site reactions for Yuflyma® was 4.9% in comparison to 7.1% for the reference biological medicine in the initial 26-week treatment period of the reported Phase III study. All of the injection site reactions that occurred with Yuflyma® were considered by the investigators to be drug-related; one reaction that was reported in a patient on Humira® was not considered to be drug-related, giving a revised incidence of 6.8%. All treatment emergent adverse effects that were classified as injection site reactions for both Humira® and Yuflyma® were considered grade 1 or 2 in terms of intensity. The proportion of patients who experienced at least one treatment emergent adverse event classified as an injection site reaction was similar across the Yuflyma® and Humira® treatment groups (5.2% versus 7.4% of patients).[17]

The EPAR concluded that from a safety point of view, Yuflyma® is considered to be similar to Humira®.[17]

Recommendation

In relation to the criterion of formulation considerations, the MMP is of the opinion that there is no robust evidence available that differentiates any of the biological medicines containing adalimumab. Yuflyma® 20 mg is therefore considered comparable to the MMP BVB medicine for adalimumab 20 mg for this criterion.

6.4 Product range including pack sizes and strengths available

The BVB medicine for adalimumab 20 mg, Amgevita®, is available on the HSE Reimbursement List in a 20 mg/0.2 millilitres (mL) PFS presentation, with one pack containing one PFS. Celltrion Healthcare Ireland have indicated in their submission that they are seeking reimbursement for the 20 mg/0.2 mL presentation of Yuflyma® under the High Tech Arrangement, with one pack containing two PFS.

Recommendation

In relation to the criterion of product range, the MMP is of the opinion that Yuflyma® 20 mg provides a similar offering when compared to the MMP BVB medicine for adalimumab 20 mg.

6.5 Product stability including storage requirements

Humira® 20 mg has a shelf life of two years.[15] Both Amgevita® 20 mg and Yuflyma® 20 mg have a shelf life of three years.[16,18] All medicinal products containing adalimumab 20 mg must be stored in a refrigerator between 2°C and 8°C, and should not be frozen.[15,16,18]

The SmPCs of Amgevita® and Humira® state that a single PFS may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The SmPCs also state that the PFS must be protected from light, and should be discarded if not used within the 14-day period.[15,18] The SmPC of Yuflyma® states that a single PFS may be stored at temperatures up to a maximum of 25°C for a period of up to 31 days. The SmPC also states that the PFS must be protected from light, and should be discarded if not used within the 31-day period.[16]

Recommendation
In relation to the criterion of product stability, the MMP is of the opinion that Yuflyma® 20 mg is comparable to the BVB medicine for adalimumab 20 mg in terms of product stability, including storage requirements.

6.6 Administration devices

The BVB medicine containing adalimumab 20 mg (Amgevita®) on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement, is available in a PFS only. Yuflyma® is also available in a PFS that delivers 20 mg of adalimumab.

Table 3 provides a summary of various properties for the administration devices of the MMP BVB medicine for adalimumab 20 mg, and for Yuflyma® 20 mg PFS.

Table 3 Characteristics of administration devices for the BVB medicine for adalimumab 20 mg (Amgevita®) and Yuflyma® 20 mg PFS

	Amgevita® 20 mg PFS*	Yuflyma® 20 mg PFS
Needle gauge†	29	29
Latex	No	No
Safety features	No	No

†A higher needle gauge is indicative of a smaller bore size for the needle, i.e. a thinner needle.
**Information is reflective of the revised formulation of Amgevita® 20 mg PFS.*

6.6.1 Pre-filled syringe

From examination of the patient information leaflet (PIL) for the PFS presentation of Yuflyma® 20 mg, the administration device appears to be comparable with that of the MMP BVB medicine for adalimumab 20 mg. Both products have a 29-gauge needle and are latex-free. There is no safety

feature in place to guard the needle upon delivery of the dose of adalimumab with Amgevita® 20 mg PFS or Yuflyma® 20 mg PFS.[16,18]

The instructions within the PIL for the administration of a dose from the PFS presentation of Yuflyma® 20 mg are clear and easy to follow. The instructions are presented in the form of pictograms with accompanying text.[16]

Recommendation
Overall, in relation to the criterion of administration devices, the MMP is of the opinion that Yuflyma® 20 mg provides a similar offering to the MMP BVB medicine for adalimumab 20 mg.

6.7 Patient factors

Celltrion Healthcare Ireland outlined the services that are available to patients when they are prescribed the biological medicine containing adalimumab 20 mg that they market.[13]

Celltrion Healthcare Ireland provide a patient support programme to patients who have been prescribed Yuflyma® 20 mg PFS.

The offerings that are available to patients who are prescribed Yuflyma® 20 mg are similar in nature to those available to patients who are prescribed the MMP BVB medicine for adalimumab 20 mg, based on the information provided to the MMP in the submission received from Celltrion Healthcare Ireland.

No robust clinical evidence was identified by the MMP that compared patient support services with each other.

Recommendation
In relation to the criterion of patient factors, the MMP is of the opinion that the patient support services offered by Celltrion Healthcare Ireland are similar in nature to those offered by the marketing authorisation holder of the MMP BVB medicine for adalimumab 20 mg.

6.8 Expenditure in the therapeutic area and potential for cost efficiencies

Biological medicines containing tumour necrosis factor-alpha (TNF-α) inhibitors were the highest expenditure category on the High Tech Arrangement in 2023, accounting for approximately €248.21 million of the total expenditure* on this scheme.[19]

Adalimumab was the most frequently prescribed of all medicines on the High Tech Arrangement (2023), with a prescribing frequency of 165,903. Total expenditure* on adalimumab was approximately €159.47 million in 2023.[19]

The proposed reimbursement price of Yuflyma® 20 mg PFS is outlined in Table 1. The submission received from Celltrion Healthcare Ireland included revised commercial terms for the PFS presentation of Yuflyma® 20 mg, resulting in a significant reduction in the acquisition cost to the HSE.

Recommendation

In relation to the criterion of expenditure in the therapeutic area and potential for cost savings, the MMP is of the opinion that for the 20 mg PFS presentation of adalimumab, the acquisition cost to the HSE for Yuflyma® 20 mg is in line with the acquisition cost of the BVB medicine for adalimumab 20 mg identified by the MMP.

6.9 Clinical guidelines

There are currently no relevant national clinical guidelines available in Ireland for the therapeutic areas or conditions for which adalimumab is indicated, i.e. dermatology, gastroenterology, ophthalmology and rheumatology.

Recommendation

In relation to the criterion of clinical guidelines, no relevant information was identified by the MMP.

6.10 Security of supply to the Irish Market

Celltrion Healthcare Ireland outlined the processes that they have in place for supply of their biosimilar medicine containing adalimumab 20 mg to the Irish market. They outlined the arrangements that they have in place for the supply chain management of Yuflyma® to the Irish market, including the distribution model that they employ.

*Total expenditure includes ingredient cost, pharmacy fees and value added tax where applicable, based on claims submitted by pharmacists.

They also outlined the arrangements that they have in place to ensure sufficient supply of Yuflyma® to the Irish market.

Recommendation
In relation to the criterion of security of supply to the Irish market, the MMP is of the opinion that Celltrion Healthcare Ireland have provided evidence of their capacity to meet the ongoing needs of Irish patients with respect to the supply of Yuflyma®.

6.11 Utilisation and clinical experience with the biological medicine

There is significant clinical experience with the use of adalimumab in the Irish setting, with approximately 14,300 patients in receipt of adalimumab 40 mg on the High Tech Arrangement in August 2024.[20] The loss of market exclusivity for Humira® took place on 16 October 2018, and biosimilar medicines containing adalimumab were added to the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement, on 1 November 2018.[11]

The MMP has identified eight BVB medicines for adalimumab 40 mg; Amgevita®, Hulio®, Hukyndra®, Humira®, Hyrimoz®[i], Idacio®, Imraldi® and Yuflyma®.[1-5,7] The MMP has identified a BVB medicine for adalimumab 20 mg; Amgevita®.[8,10] The MMP has also identified BVB medicines for adalimumab 80 mg; Amgevita®, Humira® and Yuflyma®.[6,9]

Medicines available on the High Tech Arrangement that are used in the specialities of dermatology, rheumatology and gastroenterology were added to the High Tech Hub in June 2019. Since then, over 25,000 patients have been initiated on, or switched to a biosimilar medicine for adalimumab or etanercept that has been recommended as a BVB medicine.[21]

Manufacturers of biosimilars must perform an extensive head-to-head comparability with the reference medicine and demonstrate to regulators that they have similar quality, safety and efficacy to the reference medicine such that there are no clinically meaningful differences between the two.[22] The European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA), in a joint statement, have confirmed that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar. Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.[23]

[i]In June 2024, the MMP received notification of the discontinuation of Hyrimoz®. It is, therefore, no longer recommended as a BVB medicine.

There has been a significant increase in the prescribing of biosimilar medicines of adalimumab under the High Tech Arrangement since June 2019. This demonstrates that significant clinical experience is being obtained for biosimilars of adalimumab in a short timeframe.

Recommendation
Overall, in relation to the criterion of utilisation and clinical experience with the biological medicine, given that Yuflyma® 20 mg has been deemed to be a biosimilar version of the reference medicine Humira®, the MMP is of the opinion that it provides a similar offering to the MMP BVB medicine for adalimumab 20 mg.

6.12 Any other relevant factors with respect to the particular INN
Celltrion Healthcare Ireland submitted information on their biosimilar pipeline under this criterion.[13]

6.12.1 Position papers
No new published position papers on the usage of biosimilars, either in general or specifically in relation to TNF-α inhibitors, were identified from the Irish clinical societies for the specialities for which adalimumab is prescribed (i.e. Irish Association of Dermatologists, Irish College of Ophthalmologists, Irish Society of Gastroenterology and Irish Society of Rheumatology) since the publication of the initial MMP BVB medicine evaluation report in May 2019.

6.12.2 Legislation/Guidance from Medicines Regulators
The MMP reviewed the legislation and guidelines from medicines regulators that relate to the prescribing and utilisation of biosimilar medicines. Pharmacist-led substitution of biological medicines is not permitted under the Health (Pricing and Supply of Medical Goods) Act 2013.[24]

The Health Products Regulatory Authority (HPRA) published an updated version of their Guide to Biosimilars for Healthcare Professionals in August 2020. This guide defines interchangeability as “the possibility of exchanging one medicine with another that is expected to have the same effect. This could mean replacing a reference medicine with a biosimilar (or vice versa), or replacing one biosimilar with another”. The guide states that, once approved, biosimilars can be used interchangeably with the reference medicine, or with biosimilars of that reference medicine.[22]

The EMA and the HMA, in a joint statement issued on 19 September 2022, have confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an

equivalent biosimilar. Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.[23]

Recommendation
In relation to the criterion of any other relevant factors, the MMP is of the opinion that no new relevant material was submitted under this criterion.

Overall Recommendation
The MMP considers Yuflyma® 20 mg to be comparable to the MMP BVB medicine for adalimumab 20 mg. The MMP recommends that Yuflyma® 20 mg is designated a BVB medicine for presentations of adalimumab 20 mg solution for injection that are available in a self-administered injection device.

7. MMP Recommendations – April 2025

The MMP recommends Amgevita® and Yuflyma® as the best-value biological medicines for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement.

Clinicians should prescribe Amgevita® or Yuflyma® when issuing a prescription for adalimumab 20 mg solution for injection on the High Tech Arrangement.

Implementation of this recommendation will lead to savings for the health service.

The MMP recommends that when issuing a prescription to a patient for adalimumab 20 mg, the clinician should prescribe Amgevita® or Yuflyma®.

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