

December 2018

## Best Value Adalimumab Decision and Uptake Recommendation

<b>Drug/Indication</b>	Adalimumab used in all CCG commissioned indications.
<b>Summary of recommendations</b>	<p>The High Cost Drugs Subgroup (HCDSG) made these recommendations following discussion on November 28<sup>th</sup> 2018:</p> <ol style="list-style-type: none"> <li>1. Amgevita®▼ is the best value adalimumab in Greater Manchester (GM).</li> <li>2. Commissioners and providers should work together to deliver the maximised saving to the GM system by facilitating a high uptake of the best value product.</li> <li>3. Out of area patients treated in GM should continue with the biosimilar adalimumab product that they were initiated on.</li> </ol>
<b>Background</b>	<p>Adalimumab is an injectable biologic medicine used to treat a variety of inflammatory conditions, e.g. rheumatoid arthritis. Over 95% of this tariff excluded high cost drug is commissioned by clinical commissioning groups (CCGs). In 2017/18, CCGs spent just under £20m on adalimumab in GM.</p> <p>The launch of biosimilar adalimumab products following European authorisations, and the loss of exclusivity of the originator product Humira® in October 2018, presents a major opportunity to bring savings to the NHS. Biosimilars are highly similar to the originator in terms of efficacy and safety, and usually have a lower acquisition cost.</p> <p>The outcome of the national tender process for adalimumab products was recently communicated and the single biosimilar adalimumab allocated by NHS England to the North West region is Amgevita®▼. The originator product Humira® will continue to be available nationwide. The NHS framework commenced on 1<sup>st</sup> December 2018 and is to continue until 30<sup>th</sup> November 2019 with options to extend that will be reviewed centrally.</p>
<b>Best value adalimumab – products consideration and evaluation</b>	<p>The HCDSG considered the adalimumab products available on the NHS framework in GM, Amgevita®▼ and Humira®, against the best value biologic criteria. These criteria included product licenses and formulation range, homecare provision, patient factors, biologic register support, patient testing and robustness of supply chain, and acquisition cost.<sup>1</sup> The HCDSG evaluated the products and decided that Amgevita®▼ is the best value adalimumab for GM.</p>
<b>Best value biologics uptake outcomes</b>	<p>The introduction of lower acquisition cost biosimilar medicines and continuous uptake contributes to market sustainability and encourages industry to invest in the introduction of novel treatments in the UK. The use of Amgevita®▼ in GM reduces the adalimumab drugs cost per patient charged to the NHS.</p> <p>In GM, under the direction of the HCDSG and with strong clinical engagement, a substantial effort was made in preparation for the rapid and coordinated uptake of best value adalimumab. It is acknowledged that the majority of GM trusts are prepared to commence prescribing Amgevita®▼ to new patients from December 2018. However, the localities may be at different stages of preparation for switching existing patients to best value adalimumab at the beginning of 2019.</p>

<b>Efficacy and safety</b>	<p>All biosimilars introduced to the UK market are currently authorised by the European Medicines Agency (EMA) which evaluates biosimilars according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines approved in the EU.<sup>ii</sup></p>
<b>Cost effectiveness/ Affordability</b>	<p>Due to the decrease in price of the originator product, the windfall brings a substantial GM saving estimated at nearly £4.8m in the current financial year. This would be followed by £7.8m until the end of November 2019 as per the framework (provided that no centralised arrangements are introduced).</p> <p>Further substantial savings are available following moving patients to Amgevita®▼. These savings amount to nearly £170k per month across the GM footprint, assuming an 80% uptake of the best value product and if no centralised arrangements are introduced.</p> <p>Commissioners and providers should work together to deliver this additional saving to the GM system by facilitating a high uptake of the best value product.</p>
<b>Monitoring</b>	<p>The rapid uptake of best value adalimumab Amgevita®▼ will support the achievement of locally set goals, which build on the NHS England commissioning framework for biologic medicines:</p> <ul style="list-style-type: none"> <li>• A positive uptake of the best value product in month 1 and growing in the first quarter</li> <li>• 80% uptake of the best value product by month 12.<sup>iii</sup></li> </ul> <p>This can subsequently help to improve the performance in the regional biosimilar uptake benchmarked nationally. The monitoring of the best value adalimumab Amgevita®▼ uptake on a GM level will be reported via HCDSG on a monthly basis from the start of the NHS framework.</p>
<b>Patient perspective</b>	<p>The use of biosimilars reduces the biologic drugs cost per patient, which in turn may help to address the needs of increasing numbers of patients requiring use of these medicines.</p> <p>The GM biosimilar adalimumab working group agreed a coordinated approach to allow continuation of treatment with biosimilar adalimumab other than Amgevita®▼. This would apply to patients settling in GM who were initiated on an alternative brand of biosimilar adalimumab elsewhere, and avoids multiple switching. A reciprocal agreement would be expected from out of area providers and commissioners in relation to patients established on Amgevita®▼ and moving to an area where Amgevita®▼ is not the first choice allocation of biosimilar adalimumab.</p>

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk and benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

### References

<sup>i</sup> GMMMG, HCDSG, Commissioning framework for biologic medicines: Defining the best value, April 2018

<sup>ii</sup> GM adalimumab working group, Newsletter 3: Greater Manchester biosimilar adalimumab project: clinical focus, July 2018

<sup>iii</sup> GMMMG, HCDSG, Commissioning framework for biological medicines: consistent implementation in Greater Manchester, October 2018