HIGH COST DRUGS SUBGROUP

GMMMG Greater Manchester Medicines Management Group

NHS

July 2017

Rituximab Biosimilar Uptake Recommendation

The High Cost Drugs Subgroup discussed the above at its meeting on June 28th 2017. The recommendation of this subgroup is as follows:

Drug/Indication	Following licensing by the European Medicines Agency (EMA) there are now two biosimilar Rituximab products available: • Truxima®▼ (500mg vial, NAPP Pharmaceuticals) • Rixathon®▼ (100mg vial and 500mg vial, Sandoz) Rituximab is a genetically engineered chimeric mouse/human monoclonal antibody representing a glycosylated immunoglobulin with human IgG1 constant regions and murine light-chain and heavy-chain variable region sequences. The antibody is produced by mammalian (Chinese hamster ovary) cell suspension culture and purified by affinity chromatography and ion exchange, including specific viral inactivation and removal procedures. Truxima®▼ and Rixathon®▼ have been assessed by the EMA as a rituximab biosimilars. The therapeutic indications as well as the dosing regimens are the same as those of the reference rituximab product i.e. Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukaemia, Granulomatosis with polyangiitia and microscopic polyangiitis and Rheumatoid Arthritis. All biological medicines, including biosimilar products, should be prescribed by brand.
Recommendation	**The group recommends the early adoption of biosimilar rituximab across the Greater Manchester Health Economy.** A GM gain share arrangement as detailed below will support the early adoption of biosimilar rituximab for CCG commissioned use across the area, **commencing on the 1st August 2017 and running for 24 months.** 1. Trusts may select the biosimilar product they wish to use on a Trust by Trust basis. 2. The Trust will charge a gain share for each invoice it submits to

	a commissioner, calculated as follows: • Gainshare charge = ("Contract price of the brand" – "Price paid for the biosimilar") x G % • G will be 50%, as this gainshare is a 50:50 arrangement. • Note that gain share is exclusive of VAT (unless VAT has been incurred by the provider trust) and other possible charges will not apply. Local commissioning arrangements may cover other aspects of the gain share and individual contracts should be checked for details. Resource implications should be considered with the lead commissioner and referenced in the contract. 3. This arrangement only applies for invoices submitted during the 24 months from the start date of the gain share arrangement which is the 1st August 2017 4. The invoice shall normally state the price of the medicine, and the gainshare element as separate lines, e.g.: • Rituximab (brand name of biosimilar): cost of biosimilar® • Rituximab (brand name of biosimilar) - gainshare: gainshare charge
Background	Rituximab is commissioned either by the CCG or NHSE dependent on the clinical indication. The majority of CCG commissioned spend on rituximab is for patients with rheumatoid arthritis (RA) in accordance with NICE TA195 (published August 2010). Other indications and unlicensed uses may require and individual funding requests (IFR).
Efficacy and Safety	The EMA states that: **A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. The European Medicines Agency (EMA) is responsible for evaluating the majority of applications to market biosimilars in the European Union (EU).** The EU has pioneered the regulation of biosimilar medicines by establishing a **solid framework** for their approval and by shaping biosimilar development globally. The evidence acquired over 10 years of clinical experience shows that biosimilars approved through EMA can be used as **safely and effectively** in all their approved indications as other biological medicines. NICE KTT 15: Ensure all biological medicines, including biosimilar medicines, are prescribed by brand name so that products cannot be automatically substituted at the point of dispensing. The choice of whether a patient receives a biosimilar or originator biological medicine rests with the responsible clinician in consultation with the patient.

Cost Effectiveness/ Affordability	The CCG commissioned spend on rituximab across GM in the last 12 months was approximately £1.85 million. The vast majority of this spend (£1.57 million) can be attributed to prescribing of the 500mg/50ml vials. Assuming use of the 500mg/50ml vial, and based on a 36.6% discount on the reference product price, switching 80% of rituximab prescribing to the biosimilar product would equate to an sum of £427,600 eligible for gain share across the Greater Manchester health economy. (Figures supplied by the GMSS, July 2017)
Monitoring	HCDSG will monitor the rate of biosimilar rituximab uptake by Provider Trust across GM on a quarterly basis and report this information to GMMMG.
Patient perspective	The use of biosimilar agents reduces the biologic drugs cost per patient, which in turn results in savings which can be reinvested into the GM health economy. GM CCGs expect that the provider ensures that patients are informed at the time of starting a treatment that if a more cost-effective version of the same or biosimilar drug becomes available, that they may be switched to an alternative version.

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

References available on request