Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) Crawley CCG and Horsham & Mid-Sussex CCG

Formulary Extension Briefing Paper for Prescribing Clinical Network

Medicine details	
Name, brand name	Rituximab (Truxima®)
Manufacturer	Napp Pharmaceuticals Limited
Licensed indication	Indicated in adults for: Responsible Commissioner: Clinical Commissioning Groups • Rheumatoid Arthritis Responsible Commissioner: NHS England • Non-Hodgkins Lymphoma, Chronic Lymphocytic Leukaema, Granulomatosis with polyangitis and microscopic polyangiitis.
Formulation	Solution for infusion • 500mg vials (will be available from April 1st 2017) • 100mg vials (expected to be available from July 2017)
Usual dosage	For Rheumatoid Arthritis: • 2 x 1000mg intravenous infusions given 2 weeks apart. • A course can be repeated if residual disease activity remains, but 24 weeks should have elapsed prior to the repeated course.

Disease and potential patient group	
Brief description of disease	**www.nice.org.uk** • Rheumatoid arthritis is a long-term disease in which joints in the body become inflamed, causing pain, swelling and stiffness. It is known as an 'autoimmune disease' because it is caused when the body's immune system, which normally fights infection, starts to attack healthy joints. At times, rheumatoid arthritis can be very painful and affect a person's ability to carry out everyday tasks. • It is not known why rheumatoid arthritis develops, and there is no cure. However, understanding of the disease has improved, and there are now effective treatments that can help ease the pain and symptoms, and slow down the disease. It is very important that treatment is started early to minimise damage to joints.

SUMMARY

Reason for formulary extension
• A biosimilar of rituximab is available to prescribers in the UK; it is licensed identically to the originator product Mabthera® for use in rheumatology and haematology indications. • CCGs are the responsible commissioners for the treatment of rheumatoid arthritis, autoimmune haemolytic anaemia (AIHA) and idiopathic thrombocytopenic purpura (ITP), with rituximab. The dose of rituximab used in rheumatoid arthritis is 1000mg (2x500mg vials) given 2 weeks apart and repeated if appropriate every 6 months. In

haematology, patients will have weekly doses of rituximab which will be dependent on the treatment regime given and also the patient's weight; 100mg vials will be used in this patient cohort.

- The 100mg vials of Truxima® will not be available until July 2017 and so using Truxima® 100mg vials in the haematology population (very small cohort of patients) will not be considered until this presentation is available.
- The new product, Truxima® ® is a biosimilar of Mabthera® with respect to quality, safety and efficacy and can be considered to be clinically equivalent to the originator product.
- All new patients in rheumatology, where treatment with the originator product MabThera® Truxima® is clinically appropriate and in line with national guidance, will be prescribed Truxima®.
- Add a sentence about switching patients in line with QIPP plans?

Tick one box
Addition to formulary **Replacement of originator product/s**

Name of product/s: Mabthera®

Evidence as necessary

European Medicines Agency (EMA)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004112/human_med_002077.jsp

- Extensive laboratory studies comparing Truxima with MabThera have shown that rituximab in Truxima is highly similar to rituximab in MabThera in terms of chemical structure, purity and biological activity.
- Because Truxima is a biosimilar medicine, the studies on effectiveness and safety carried out for MabThera do not need to be repeated for Truxima. Truxima has been compared with MabThera given into a vein in a study involving 372 patients with active rheumatoid arthritis. The study showed that Truxima and MabThera led to similar levels of rituximab in the blood. In addition, the two medicines had comparable effects on arthritis symptoms: after 24 weeks, the proportion of patients with a 20% improvement in symptom score (called ACR20) was 74% (114 of 155 patients) with Truxima and 73% (43 of 59 patients) with MabThera. Supportive studies in patients with rheumatoid arthritis and in patients with advanced follicular lymphoma also indicated that the medicines produced similar responses

Cost implications

Cost of product: (excluding VAT)

Annual cost per patient: Truxima®
Costing information (unconfirmed) below provided by Regional Medicines Procurement Specialist Pharmacist

- £1,988 /course of treatment.
- £3,976 /year (2 courses)/patient

Availability of PAS and details (if appropriate):
There is no PAS. The cost of Truxima® is believed to be 43% less than the current price of MabThera®.

Availability of homecare service (if appropriate): No

Alternative treatments and cost per (patient per year / per month as appropriate)

Mabthera® (Inclusive of VAT)

- £4,191.12 / course of treatment
- £8,382.24/year (potential 2 courses)/patient

Impact to patients

- Use of the biosimilar medicine will be discussed with the patient by the clinical team; informed consent should be given by the patient.
- There should be no clinical reason why a patient should not be initiated onto the biosimilar medicine at their next treatment course.

Impact to primary care

- This is a PbRe drug and is commissioned by either CCGs or NHS England for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving rituximab (Truxima® ®), and this information should be uploaded to the clinical system, in order for the primary care prescriber to be alerted to any potential side-effects and interactions with other medicines prescribed in primary care.

Impact to secondary care

- Infusion rates – when given for the first time rituximab should be given slowly (50mg/hour) and then subsequent infusions can be given at 100mg/hour. As Truxima® ® is a new biosimlar medicine, the specialists may give the first infusion of Truxima®at the lower rate, even if a patient has received previous doses of rituximab. There could be capacity issues although numbers are expected to be small.
- Provider pharmacies will be able to use remaining stock of 500mg vials of Mabthera® for haematology indications so there will be no issues with regards stocks (confirmed with providers)
- The Medicines and Healthcare Products Regulatory Agency (MHRA) recommends that it is good practice to prescribe biological products by brand name to ensure that substitution of a biosimilar product does not occur when the medicine is dispensed by the pharmacist.
- Blueteq forms will be developed for Truxima® and will be available for specialists to complete.
- Originator product forms will be amended to include any clinical exceptions where a patient could be initiated on the originator product over the biosimilar.

Impact to CCGs

www.nice.org.uk
https://www.nice.org.uk/guidance/ktt15/resources/biosimilar-medicines-58757954414533

- Biosimilar medicines have the potential to offer the NHS considerable cost savings and widen the access to innovative medicines.

Implementation

- There has been a discussion with all local stakeholders in relation to the use of the biosimilar medicine during April 2017.
- Provider pharmacists agreed to liaise with specialists and put processes in place to ensure smooth transition over to Truxima® during April 2017.
- Truxima® will be used in Rheumatology initially because of lack of availability of the 100mg vials (expected from July 2017).
- Any incentives offered for using the biosimilar medicine should be provided to improve patient care in the speciality using the medicine. Providers will need to have internal discussions to ensure that the incentives offered by commissioners are given to the speciality.
- There will need to be a Prescribing Advisory Database (PAD) entry made for this product and a policy statement uploaded to the entry with the rheumatoid arthritis

treatment pathway. Reference to the biosimilar should be made in the RA treatment pathway.
Recommendation to PCN
PbRe: Yes **Recommended traffic light status (see attached guidelines):** **RED** **Additional comments:** Blueteq forms will need to be developed for this product

References:

Prepared by:

Clare Johns Lead Commissioning Technician, Pharmaceutical Commissioning Team, Surrey Downs CCG hosted service

Declaration of Interest:

None

Date: 30/03/2017

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

XXXX

Date: XXXX

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	*30/03/2017*	*Clare Johns*	*First draft*	*For discussion at PCN. Discussed by local providers and commissioners at a telephone conference recently.*