

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

PRESCRIBER

Name:

Ward:

PATIENT:

Name:

NHI:

Rituximab (Mabthera)

INITIATION – rheumatoid arthritis - prior TNF inhibitor use

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

☐ The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis

and

☐ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

☐ Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis

and

☐ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy

or

☐ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

☐ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

I confirm that the above details are correct:

Signed: Date:

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Name:

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Rituximab (Mabthera) - continued

INITIATION – rheumatoid arthritis - TNF inhibitors contraindicated

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ☐ Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated
- and
- ☐ Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer
- and
- ☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose
- and
- ☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses)
- and
- ☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of cyclosporin
- or
- ☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold
- or
- ☐ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate
- and
- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints
- or
- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip
- and
- ☐ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application
- or
- ☐ C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months
- and
- ☐ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy
- or
- ☐ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used
- and
- ☐ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

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Name:

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Rituximab (Mabthera) - *continued*

CONTINUATION – rheumatoid arthritis - re-treatment in 'partial responders' to rituximab

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ☐ At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
- or
- ☐ At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
- or
- ☐ At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ☐ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

- ☐ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy
- or
- ☐ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ☐ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

CONTINUATION – rheumatoid arthritis - re-treatment in 'responders' to rituximab

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ☐ At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
- or
- ☐ At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ☐ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

- ☐ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy
- or
- ☐ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ☐ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

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Signed: Date: