HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

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: .....

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) - *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

I confirm that the above details are correct:

Signed: ..... Date: .....

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) - *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

I confirm that the above details are correct:

Signed: ..... Date: .....