RS2194 - Rituximab

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 (Riximyo)

INITIATION – haemophilia with inhibitors

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has mild congenital haemophilia complicated by inhibitors

or

- ○ Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy

or

- ○ Patient has acquired haemophilia

CONTINUATION – haemophilia with inhibitors

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient was previously treated with rituximab for haemophilia with inhibitors

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

INITIATION – post-transplant

Prerequisites (tick boxes where appropriate)

- ○ The patient has B-cell post-transplant lymphoproliferative disorder*

and

- ○ To be used for a maximum of 8 treatment cycles

Note: Indications marked with * are unapproved indications.

CONTINUATION – post-transplant

Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more

and

- ○ The patient has B-cell post-transplant lymphoproliferative disorder*

and

- ○ To be used for no more than 6 treatment cycles

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

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NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

or

- ○ The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

CONTINUATION – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more
- **and**
- ○ The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for no more than 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

INITIATION – aggressive CD20 positive NHL
Prerequisites (tick boxes where appropriate)

- ○ The patient has treatment naive aggressive CD20 positive NHL
- **and**
- ○ To be used with a multi-agent chemotherapy regimen given with curative intent
- **and**
- ○ To be used for a maximum of 8 treatment cycles

or

- ○ The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – aggressive CD20 positive NHL

Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more

and

- ○ The patient has relapsed refractory/aggressive CD20 positive NHL

and

- ○ To be used with a multi-agent chemotherapy regimen given with curative intent

and

- ○ To be used for a maximum of 4 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

INITIATION – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment

and

- ○ The patient is rituximab treatment naive

or

- ○ The patient is chemotherapy treatment naive

or

- ○ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment

and

- ○ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy

or

- ○ The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax

and

- ○ The patient has good performance status

and

- ○ Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles

and

- ○ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – Chronic lymphocytic leukaemia
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax

or

- ○ The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL

and

- ○ The patient has had an interval of 36 months or more since commencement of initial rituximab treatment

and

- ○ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustin

and

- ○ Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

INITIATION – severe cold haemagglutinin disease (CHAD)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has cold haemagglutinin disease*

and

- ○ Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

CONTINUATION – severe cold haemagglutinin disease (CHAD)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for severe cold haemagglutinin disease*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – warm autoimmune haemolytic anaemia (warm AIHA)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has warm autoimmune haemolytic anaemia*

and

- ○ One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

CONTINUATION – warm autoimmune haemolytic anaemia (warm AIHA)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

INITIATION – immune thrombocytopenic purpura (ITP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre

or

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding

and

- ○ Treatment with steroids and splenectomy have been ineffective

or

- ○ Treatment with steroids has been ineffective and splenectomy is an absolute contraindication

or

- ○ Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy)

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – immune thrombocytopenic purpura (ITP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for immune thrombocytopenic purpura*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

INITIATION – thrombotic thrombocytopenic purpura (TTP)
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The total rituximab dose per cycle would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

and

- ○ Each treatment cycle at least 6 months apart

and

- ○ Patient has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange

or

- ○ Patient has acute idiopathic TTP* with neurological or cardiovascular pathology

Note: Indications marked with * are unapproved indications.

INITIATION – pure red cell aplasia (PRCA)
Re-assessment required after 6 weeks
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder

Note: Indications marked with * are unapproved indications.

CONTINUATION – pure red cell aplasia (PRCA)
Re-assessment required after 6 weeks
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

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PATIENT:

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Rituximab (Riximyo) - *continued*

INITIATION – ANCA associated vasculitis
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with ANCA associated vasculitis*

and

- ○ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks

and

- ○ Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months

or

- ○ Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g

or

- ○ Cyclophosphamide and methotrexate are contraindicated

or

- ○ Patient is a female of child-bearing potential

or

- ○ Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy

Note: Indications marked with * are unapproved indications.

CONTINUATION – ANCA associated vasculitis
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with ANCA associated vasculitis*

and

- ○ Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis

and

- ○ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

INITIATION – treatment refractory systemic lupus erythematosus (SLE)
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe, immediately life- or organ-threatening SLE*

and

- ○ The condition has been refractory to treatment with corticosteroids at a dose of at least 1 mg/kg unless contraindicated

and

- ○ The condition has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated

and

- ○ Initial treatment maximum of four 1000 mg infusions

and

- ○ Treatment for relapse following initial partial response to rituximab up to a maximum of two 1000 mg infusions every 6 months

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Rixiмyo) - *continued*

INITIATION – Antibody-mediated organ transplant rejection
Prerequisites (tick box where appropriate)

◯ Patient has been diagnosed with antibody-mediated organ transplant rejection*

Note: Indications marked with * are unapproved indications.

INITIATION – ABO-incompatible organ transplant
Prerequisites (tick box where appropriate)

◯ Patient is to undergo an ABO-incompatible solid organ transplant*

Note: Indications marked with * are unapproved indications.

INITIATION – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

◯ Patient is a child with SDNS* or FRNS*

and

◯ Treatment with corticosteroids, ciclosporin, and mycophenolate for at least 3 months for each agent has been ineffective, not tolerated, or is contraindicated

and

◯ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

CONTINUATION – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

◯ Patient who was previously treated with rituximab for nephrotic syndrome*

and

◯ Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment

and

◯ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

INITIATION – Steroid resistant nephrotic syndrome (SRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

◯ Patient is a child with SRNS* and treatment with corticosteroids, ciclosporin and tacrolimus for at least 3 months for each agent has been ineffective, not tolerated, or is contraindicated

and

◯ Genetic causes of nephrotic syndrome have been excluded

and

◯ The total rituximab dose per cycle would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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Name: .....

Ward: .....

PATIENT:

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NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – Steroid resistant nephrotic syndrome (SRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient who was previously treated with rituximab for nephrotic syndrome*

and

- ○ Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

INITIATION – Neuromyelitis Optica Spectrum Disorder (NMOSD)
Prerequisites (tick boxes where appropriate)

- ○ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

- ○ Patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms with supporting clinical investigations)

or

- ○ Patient has experienced a breakthrough attack of NMOSD

and

- ○ Patient is receiving treatment with mycophenolate unless contraindicated or not tolerated

and

- ○ Patient is receiving treatment with corticosteroids unless contraindicated or not tolerated

and

- ○ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

INITIATION – refractory myasthenia gravis*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

- ○ Treatment with corticosteroids and at least one other immunosuppressant for a minimum period of 12 months has been ineffective

or

- ○ Treatment with at least one other immunosuppressant for a period of at least 12 months

and

- ○ Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Rixiimyo) - *continued*

CONTINUATION – refractory myasthenia gravis*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ❍ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

- ❍ An initial response lasting at least 12 months was demonstrated

and

- ❍ Patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months

or

- ❍ Patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months

and

- ❍ Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects

Note: Indications marked with * are unapproved indications.

INITIATION – antisynthetase syndrome
Prerequisites (tick boxes where appropriate)

- ❍ Patient has severe, immediately life- or organ-threatening disease, including interstitial lung disease

and

- ❍ Treatment with at least 3 immunosuppressants (oral corticosteroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has been ineffective controlling active disease

or

- ❍ Rapid treatment is required for life threatening complications

and

- ❍ Maximum of two 1000 mg infusions every 6 months

INITIATION – graft versus host disease
Prerequisites (tick boxes where appropriate)

- ❍ Patient has refractory graft versus host disease following transplant

and

- ❍ Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease

and

- ❍ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – chronic inflammatory demyelinating polyneuropathy (CIPD)*

Prerequisites (tick boxes where appropriate)

○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

○ Treatment with corticosteroids and intravenous immunoglobulin and/or plasma exchange has been ineffective controlling active disease, is not tolerated, or is contraindicated

and

○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) is not tolerated or has been ineffective controlling active disease. If an immunosuppressant is contraindicated, a trial has occurred of one of those which is not contraindicated (unless all are contraindicated)

or

○ Rapid treatment is required for life threatening complications

and

○ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

○ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

INITIATION – anti-NMDA receptor autoimmune encephalitis*

Prerequisites (tick boxes where appropriate)

○ Treatment with corticosteroids and intravenous immunoglobulin and/or plasma exchange has been ineffective controlling active disease, is not tolerated or is contraindicated

and

○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has been ineffective controlling active disease, is not tolerated or is contraindicated

or

○ Rapid treatment is required for life threatening complications

and

○ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

○ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

INITIATION – CD20+ low grade or follicular B-cell NHL

Re-assessment required after 9 months

Prerequisites (tick boxes where appropriate)

○ The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy

and

○ To be used for a maximum of 6 treatment cycles

or

○ The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy

and

○ To be used for a maximum of 6 treatment cycles

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Rixiimyo) - *continued*

CONTINUATION – CD20+ low grade or follicular B-cell NHL
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy

and

- ○ Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m^2 every 8 weeks (maximum of 12 cycles)

INITIATION – Membranous nephropathy
Prerequisites (tick boxes where appropriate)

- ○ Patient has biopsy-proven primary/idiopathic membranous nephropathy*

or

- ○ Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m^2

and

- ○ Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures that include (unless contraindicated or the patient has experienced intolerable side effects) renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents

and

- ○ The total rituximab dose per cycle would not exceed the equivalent of 375mg/m^2 of body surface area per week for a total of 4 weeks

and

- ○ Subsequent retreatment only for disease relapse or after partial response

Note: Indications marked with * are unapproved indications.

INITIATION – B-cell acute lymphoblastic leukaemia/lymphoma*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma*

and

- ○ Treatment must be in combination with an intensive chemotherapy protocol with curative intent

and

- ○ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 per dose for a maximum of 18 doses

Note: Indications marked with * are unapproved indications.

INITIATION – desensitisation prior to transplant
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient requires desensitisation prior to mismatched allogenic stem cell transplant*

and

- ○ Patient would receive no more than two doses at 375 mg/m^2 of body-surface area

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – pemiphigus*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe rapidly progressive pemphigus

and

- ○ Is used in combination with systemic corticosteroids (20 mg/day)

and

- ○ Skin involvement is at least 5% body surface area

or

- ○ Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions

or

- ○ Involvement of two or more mucosal sites

or

- ○ Patient has pemphigus

and

- ○ Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated

Note: Indications marked with * are unapproved indications.

CONTINUATION – pemiphigus*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of skin ulceration and reduction in corticosteroid requirement

and

- ○ Patient has not received rituximab in the previous 6 months

Note: Indications marked with * are unapproved indications.

INITIATION – immunoglobulin G4-related disease (IgG4-RD*)
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has confirmed diagnosis of IgG4-RD*

and

- ○ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse

or

- ○ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance

and

- ○ Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

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 (Riximyo) - *continued*

CONTINUATION – immunoglobulin G4-related disease (IgG4-RD*)
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ❍ Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed

or

- ❍ Patient is receiving maintenance treatment for IgG4-RD*

and

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

and

- ❍ Maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

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