**RS1973 - Rituximab**



NOSPIN

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.

HOSPITAL

I confirm that the above details are correct:

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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

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.

HOSPITAL

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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 within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax

**and**

- ○ The patient has good performance status

**and**

- ○ The patient does not have chromosome 17p deletion CLL

**or**

- ○ Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia

**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.

HOSPITAL

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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 within 36 months of previous treatment 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**

- ○ The patient does not have chromosome 17p deletion CLL

**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/m2 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.

I confirm that the above details are correct:

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

HOSPITAL

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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/m2 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/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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HOSPITAL

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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)**
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**

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

**and**

- ○ Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange

**or**

- ○ Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology

Note: Indications marked with * are unapproved indications.

**CONTINUATION – thrombotic thrombocytopenic purpura (TTP)**
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 was previously treated with rituximab for thrombotic thrombocytopenic purpura*

**and**

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

**and**

- ○ Patient now requires repeat treatment

**and**

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

**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.

**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.

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HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

**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**

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

**and**

- ○ The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg

**and**

- ○ The disease 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**

- ○ Maximum of four 1000 mg infusions of rituximab

Note: Indications marked with * are unapproved indications.

**CONTINUATION – 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's SLE* achieved at least a partial response to the previous round of prior rituximab treatment

**and**

- ○ The disease has subsequently relapsed

**and**

- ○ Maximum of two 1000 mg infusions of rituximab

Note: Indications marked with * are unapproved indications.

**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.

HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

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

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

**and**

- ○ Patient is a child with SDNS* or FRNS*

**and**

- ○ Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity

**and**

- ○ Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects

**and**

- ○ Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses

**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 a * 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)

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

**and**

- ○ 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 a * are unapproved indications.

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

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

**and**

- ○ Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective

**and**

- ○ Treatment with tacrolimus for at least 3 months has been ineffective

**and**

- ○ Genetic causes of nephrotic syndrome have been excluded

**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 a * are unapproved indications.

HOSPITAL

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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

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

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

**and**

- ○ 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 a * are unapproved indications.

**INITIATION – Neuromyelitis Optica Spectrum Disorder (NMOSD)**
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ○ One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks

**and**

- ○ The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD)

**or**

- ○ The patient has experienced a breakthrough attack of NMOSD

**and**

- ○ The patient is receiving treatment with mycophenolate

**and**

- ○ The patients is receiving treatment with corticosteroids

**CONTINUATION – Neuromyelitis Optica Spectrum Disorder (NMOSD)**
Re-assessment required after 2 years
**Prerequisites** (tick boxes where appropriate)

- ○ One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks

**and**

- ○ The patients has responded to the most recent course of rituximab

**and**

- ○ The patient has not received rituximab in the previous 6 months

HOSPITAL

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*

**INITIATION – Severe Refractory Myasthenia Gravis**
Re-assessment required after 2 years
**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**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

**and**

- ○ Treatment with corticosteroids and at least one other immunosuppressant for at least a 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

**CONTINUATION – Severe Refractory Myasthenia Gravis**
Re-assessment required after 2 years
**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**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

**and**

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

**and**

- ○ The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months

**or**

- ○ The 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

**INITIATION – Severe antisynthetase syndrome**
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ○ Patient has confirmed antisynthetase syndrome

**and**

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

**and**

- ○ Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease

**or**

- ○ Rapid treatment is required due to life threatening complications

**and**

- ○ Maximum of four 1,000 mg infusions of rituximab

I confirm that the above details are correct:

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

HOSPITAL

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** (Rixiмyo) - *continued*

**CONTINUATION – Severe antisynthetase syndrome**
Re-assessment required after 12 months
**Prerequisites** (tick boxes where appropriate)

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function

**and**

- ○ The patient has not received rituximab in the previous 6 months

**and**

- ○ Maximum of two cycles of 2 × 1,000 mg infusions of rituximab given two weeks apart

**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

**INITIATION – severe chronic inflammatory demyelinating polyneuropathy**
Re-assessment required after 6 months
**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**

- ○ Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD)

**and**

- ○ Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease

**and**

- ○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease

**or**

- ○ Rapid treatment is required due to life threatening complications

**and**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

**CONTINUATION – severe chronic inflammatory demyelinating polyneuropathy**
Re-assessment required after 6 months
**Prerequisites** (tick boxes where appropriate)

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline

**and**

- ○ The patient has not received rituximab in the previous 6 months

**and**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

I confirm that the above details are correct:

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

HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Rixiimyo) - *continued*

**INITIATION – anti-NMDA receptor autoimmune encephalitis**
Re-assessment required after 6 months
**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**

- ○ Patient has severe anti-NMDA receptor autoimmune encephalitis

**and**

- ○ Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease

**and**

- ○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease

**or**

- ○ Rapid treatment is required due to life threatening complications

**and**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

**CONTINUATION – anti-NMDA receptor autoimmune encephalitis**
Re-assessment required after 6 months
**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**

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function

**and**

- ○ The patient has not received rituximab in the previous 6 months

**and**

- ○ The patient has experienced a relapse and now requires further treatment

**and**

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

**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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HOSPITAL

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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/m2 every 8 weeks (maximum of 12 cycles)

**INITIATION – Membranous nephropathy**
Re-assessment required after 6 weeks
**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/1.73m2

**and**

- ○ Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note)

**and**

- ○ The total rituximab dose would not exceed the equivalent of 375mg/m2 of body surface area per week for a total of 4 weeks

**CONTINUATION – Membranous nephropathy**
Re-assessment required after 6 weeks
**Prerequisites** (tick boxes where appropriate)

- ○ Patient was previously treated with rituximab for membranous nephropathy*

**and**

- ○ Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment

**or**

- ○ Patient achieved partial response to treatment and requires repeat treatment (see Note)

**and**

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note:

a) Indications marked with * are unapproved indications.

b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.

c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.

d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

**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/m2 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/m2 of body-surface area

Note: Indications marked with * are unapproved indications.

**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.

HOSPITAL

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

## **Rituximab** (Riximyo) - *continued*

**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.

**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.

HOSPITAL

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