SA2233 - Rituximab

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
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Rituximab (Riximyo)

Initial application — ABO-incompatible organ transplant
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

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

Note: Indications marked with * are unapproved indications.

Initial application — ANCA associated vasculitis
Applications from any relevant practitioner. Approvals valid for 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.

Renewal — ANCA associated vasculitis

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

Initial application — Antibody-mediated organ transplant rejection
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

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

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — Chronic lymphocytic leukaemia
Applications from any relevant practitioner. Approvals valid for 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.

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Rituximab (Riximyo) - *continued*

Renewal — Chronic lymphocytic leukaemia

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 bendamustine

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.

Initial application — Neuromyelitis Optica Spectrum Disorder(NMOSD)

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

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Rituximab (Riximyo) - *continued*

Renewal — Neuromyelitis Optica Spectrum Disorder

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

Initial application — Post-transplant

Applications from any relevant practitioner. Approvals valid for 12 months.

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.

Renewal — Post-transplant

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 9 months.

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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Rituximab (Riximyo) - *continued*

Initial application — Severe Refractory Myasthenia Gravis
Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

☐ 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

Renewal — Severe Refractory Myasthenia Gravis

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

☐ 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

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Rituximab (Riximyo) - *continued*

Initial application — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ 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 * are unapproved indications.

Renewal — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Current approval Number (if known):.....

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 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.

Initial application — Steroid resistant nephrotic syndrome (SRNS)
Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ 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 * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Renewal — Steroid resistant nephrotic syndrome (SRNS)

Current approval Number (if known):.....

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 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.

Initial application — aggressive CD20 positive NHL

Applications from any relevant practitioner. Approvals valid for 12 months.

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

Renewal — aggressive CD20 positive NHL

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 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

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Rituximab (Riximyo) - *continued*

Initial application — haemophilia with inhibitors
Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Renewal — haemophilia with inhibitors

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Initial application — immune thrombocytopenic purpura (ITP)
Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ 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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Rituximab (Riximyo) - *continued*

Renewal — immune thrombocytopenic purpura (ITP)

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

Prerequisites(tick boxes where appropriate)

☐ 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.

Initial application — indolent, low-grade lymphomas or hairy cell leukaemia*

Applications from any relevant practitioner. Approvals valid for 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.

Renewal — indolent, low-grade lymphomas or hairy cell leukaemia*

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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Rituximab (Riximyo) - *continued*

Initial application — pure red cell aplasia (PRCA)
Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks.
Prerequisites(tick box where appropriate)

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

Note: Indications marked with * are unapproved indications.

Renewal — pure red cell aplasia (PRCA)

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks.
Prerequisites(tick box where appropriate)

☐ 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.

Initial application — severe cold haemagglutinin disease (CHAD)
Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

☐ 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.

Renewal — severe cold haemagglutinin disease (CHAD)

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

☐ 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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Rituximab (Riximyo) - *continued*

Initial application — thrombotic thrombocytopenic purpura (TTP)
Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ 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.

Renewal — thrombotic thrombocytopenic purpura (TTP)

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ 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.

Initial application — treatment refractory systemic lupus erythematosus (SLE)
Applications only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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.

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Rituximab (Riximyo) - *continued*

Renewal — treatment refractory systemic lupus erythematosus (SLE)

Current approval Number (if known):.....

Applications only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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.

Initial application — warm autoimmune haemolytic anaemia (warm AIHA)

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

Prerequisites(tick boxes where appropriate)

- ☐ 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.

Renewal — warm autoimmune haemolytic anaemia (warm AIHA)

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

Prerequisites(tick boxes where appropriate)

- ☐ 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.

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Rituximab (Riximyo) - *continued*

Initial application — severe antisynthetase syndrome
Applications from any relevant practitioner. Approvals valid for 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 1,000mg infusions of rituximab

Renewal — severe antisynthetase syndrome

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 × 1,000mg infusions of rituximab given two weeks apart

Initial application — graft versus host disease
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....
Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Rituximab (Riximyo) - *continued*

Initial application — severe chronic inflammatory demyelinating polyneuropathy
Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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

Renewal — severe chronic inflammatory demyelinating polyneuropathy

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 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

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Rituximab (Riximyo) - *continued*

Initial application — anti-NMDA receptor autoimmune encephalitis
Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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

Renewal — anti-NMDA receptor autoimmune encephalitis

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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

Initial application — CD20+ low grade or follicular B-cell NHL
Applications from any relevant practitioner. Approvals valid for 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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Rituximab (Riximyo) - *continued*

Renewal — CD20+ low grade or follicular B-cell NHL

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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)

Initial application — Membranous nephropathy

Applications only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 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

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Rituximab (Riximyo) - *continued*

Renewal — Membranous nephropathy

Current approval Number (if known):.....

Applications only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 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.

Initial application — B-cell acute lymphoblastic leukaemia/lymphoma*

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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.

Initial application — desensisation prior to transplant

Applications from any relevant practitioner. Approvals valid for 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.

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Rituximab (Riximyo) - *continued*

Initial application — pemiphigus*
Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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.

Renewal — pemiphigus*

Current approval Number (if known):.....

Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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.

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Rituximab (Riximyo) - *continued*

Initial application — immunoglobulin G4-related disease (IgG4-RD*)
Applications from any relevant practitioner. Approvals valid for 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.

Renewal — immunoglobulin G4-related disease (IgG4-RD*)

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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