SA2689 - Rituximab

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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 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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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 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 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 from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 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.

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Rituximab (Riximyo) - *continued*

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.

Initial application — refractory myasthenia gravis*
Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 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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Rituximab (Riximyo) - *continued*

Renewal — refractory myasthenia gravis*

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

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 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.

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

Applications from any relevant practitioner. Approvals valid for 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.

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

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

Applications from any relevant practitioner. 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.

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Rituximab (Riximyo) - *continued*

Initial application — Steroid resistant nephrotic syndrome (SRNS)
Applications from any relevant practitioner. Approvals valid for 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.

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

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Rituximab (Riximyo) - *continued*

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

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

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Rituximab (Riximyo) - *continued*

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/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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.

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Rituximab (Riximyo) - *continued*

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.

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.

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Rituximab (Riximyo) - *continued*

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/m^2 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.

Initial application — thrombotic thrombocytopenic purpura (TTP)*
Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ 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

or

- ☐ Patient has a history of immune-mediated thrombotic thrombocytopenic purpura, currently in clinical remission but has demonstrated a decline in ADAMTS13 levels or equivalent, consistent with high risk of relapse

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — treatment refractory systemic lupus erythematosus (SLE)*
Applications only from a rheumatologist, nephrologist or any relevant practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ 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.

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/m^2 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 — antisynthetase syndrome
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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 1000mg infusions every 6 months

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

Initial application — chronic inflammatory demyelinating polyneuropathy (CIPD)*
Applications only from a neurologist or any relevant practitioner on the recommendation of a neurologist. Approvals valid without further renewal unless notified.
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) 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.

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

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

APPLICANT (stamp or sticker acceptable)

Reg No: .....

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Rituximab (Riximyo) - *continued*

Initial application — anti-NMDA receptor autoimmune encephalitis*
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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.

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

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/m^2 every 8 weeks (maximum of 12 cycles)

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

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

Initial application — Membranous nephropathy
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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 375 mg/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.

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/m^2 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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Signed: ..... Date: .....