

SA2233 - 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/m² 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/m² 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 patient 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/m² 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/m² 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/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 — 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Patient who was previously treated with rituximab for nephrotic syndrome* |
| and | |
| <input type="checkbox"/> | 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 | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | The patient has treatment naive aggressive CD20 positive NHL |
| and | |
| <input type="checkbox"/> | To be used with a multi-agent chemotherapy regimen given with curative intent |
| and | |
| <input type="checkbox"/> | To be used for a maximum of 8 treatment cycles |
| or | |
| <input type="checkbox"/> | The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | The patient has had a rituximab treatment-free interval of 12 months or more |
| and | |
| <input type="checkbox"/> | The patient has relapsed refractory/aggressive CD20 positive NHL |
| and | |
| <input type="checkbox"/> | To be used with a multi-agent chemotherapy regimen given with curative intent |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | Patient has mild congenital haemophilia complicated by inhibitors |
| or | |
| <input type="checkbox"/> | Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy |
| or | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | Patient was previously treated with rituximab for haemophilia with inhibitors |
| and | |
| <input type="checkbox"/> | An initial response lasting at least 12 months was demonstrated |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre |
| or | |
| <input type="checkbox"/> | Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding |
| and | |
| <input type="checkbox"/> | Treatment with steroids and splenectomy have been ineffective |
| or | |
| <input type="checkbox"/> | Treatment with steroids has been ineffective and splenectomy is an absolute contraindication |
| or | |
| <input type="checkbox"/> | Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy) |
| and | |
| <input type="checkbox"/> | 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 — 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | 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 | |
| <input type="checkbox"/> | Patient was previously treated with rituximab for immune thrombocytopenic purpura* |
| and | |
| <input type="checkbox"/> | An initial response lasting at least 12 months was demonstrated |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy |
| and | |
| <input type="checkbox"/> | To be used for a maximum of 6 treatment cycles |
| or | |
| <input type="checkbox"/> | The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | The patient has had a rituximab treatment-free interval of 12 months or more |
| and | |
| <input type="checkbox"/> | The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy |
| and | |
| <input type="checkbox"/> | 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/m² 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.

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

Signed: Date:

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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/m² 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | Patient has confirmed antisynthetase syndrome |
| and | |
| <input type="checkbox"/> | Patient has severe, immediately life or organ threatening disease, including interstitial lung disease |
| and | |
| <input type="checkbox"/> | Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease |
| or | |
| <input type="checkbox"/> | Rapid treatment is required due to life threatening complications |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function |
| and | |
| <input type="checkbox"/> | The patient has not received rituximab in the previous 6 months |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Patient has refractory graft versus host disease following transplant |
| and | |
| <input type="checkbox"/> | Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease |
| and | |
| <input type="checkbox"/> | The total rituximab dose used would not exceed the equivalent of 375 mg/m ² of body surface area per week for a total of 4 weeks |

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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/m² per dose for a maximum of 18 doses

Note: Indications marked with * are unapproved indications.

Initial application — desensitisation 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 — pemphigus*

Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

| | |
|--|---|
| <input type="checkbox"/> Patient has severe rapidly progressive pemphigus and <input type="checkbox"/> Is used in combination with systemic corticosteroids (20 mg/day) and | <input type="checkbox"/> Skin involvement is at least 5% body surface area or <input type="checkbox"/> Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions or <input type="checkbox"/> Involvement of two or more mucosal sites |
| or | |
| <input type="checkbox"/> Patient has pemphigus and <input type="checkbox"/> 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 — pemphigus*

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

Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

| |
|--|
| <input type="checkbox"/> Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of skin ulceration and reduction in corticosteroid requirement and <input type="checkbox"/> 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Patient has confirmed diagnosis of IgG4-RD* |
| and | |
| <input type="checkbox"/> | 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 | |
| <input type="checkbox"/> | Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance |
| and | |
| <input type="checkbox"/> | 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)

| | |
|--------------------------|---|
| <input type="checkbox"/> | Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed |
| or | |
| <input type="checkbox"/> | Patient is receiving maintenance treatment for IgG4-RD* |
| and | |
| <input type="checkbox"/> | Rituximab re-treatment not to be given within 6 months of previous course of treatment |
| and | |
| <input type="checkbox"/> | Maximum of two 1000 mg infusions of rituximab given two weeks apart |

Note: Indications marked with * are unapproved indications.

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