

## 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)

<input type="checkbox"/> Patient has been diagnosed with ANCA associated vasculitis*
<b>and</b>
<input type="checkbox"/> The total rituximab dose would not exceed the equivalent of 375 mg/m <sup>2</sup> of body-surface area per week for a total of 4 weeks
<b>and</b>
<input type="checkbox"/> Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months
<b>or</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> Cyclophosphamide and methotrexate are contraindicated
<b>or</b>
<input type="checkbox"/> Patient is a female of child-bearing potential
<b>or</b>
<input type="checkbox"/> 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)

<input type="checkbox"/> Patient has been diagnosed with ANCA associated vasculitis*
<b>and</b>
<input type="checkbox"/> Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis
<b>and</b>
<input type="checkbox"/> The total rituximab dose would not exceed the equivalent of 375 mg/m <sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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*
<b>and</b>	
<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
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose used would not exceed the equivalent of 375 mg/m <sup>2</sup> 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
<b>and</b>	
<input type="checkbox"/>	To be used with a multi-agent chemotherapy regimen given with curative intent
<b>and</b>	
<input type="checkbox"/>	To be used for a maximum of 8 treatment cycles
<b>or</b>	
<input type="checkbox"/>	The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy
<b>and</b>	
<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
<b>and</b>	
<input type="checkbox"/>	The patient has relapsed refractory/aggressive CD20 positive NHL
<b>and</b>	
<input type="checkbox"/>	To be used with a multi-agent chemotherapy regimen given with curative intent
<b>and</b>	
<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)

- 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/m<sup>2</sup> 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 <sup>2</sup> 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/m<sup>2</sup> 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<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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<sup>2</sup> 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
<b>and</b>	
<input type="checkbox"/>	Patient has severe, immediately life or organ threatening disease, including interstitial lung disease
<b>and</b>	
<input type="checkbox"/>	Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease
<b>or</b>	
<input type="checkbox"/>	Rapid treatment is required due to life threatening complications
<b>and</b>	
<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
<b>and</b>	
<input type="checkbox"/>	The patient has not received rituximab in the previous 6 months
<b>and</b>	
<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
<b>and</b>	
<input type="checkbox"/>	Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose used would not exceed the equivalent of 375 mg/m <sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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)

<input type="checkbox"/>	Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy
<b>and</b>	
<input type="checkbox"/>	Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m <sup>2</sup> 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)

<input type="checkbox"/>	Patient has biopsy-proven primary/idiopathic membranous nephropathy*
<b>or</b>	
<input type="checkbox"/>	Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m <sup>2</sup>
<b>and</b>	
<input type="checkbox"/>	Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note)
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose would not exceed the equivalent of 375mg/m <sup>2</sup> 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/m<sup>2</sup> 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<sup>2</sup> 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/m<sup>2</sup> 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)

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 — pemphigus\***

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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