

## SA2641 - 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<sup>2</sup> 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<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 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<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 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<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*

**Initial application — Steroid resistant nephrotic syndrome (SRNS)**

Applications from any relevant practitioner. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Genetic causes of nephrotic syndrome have been excluded
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose per cycle 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 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

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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)

<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

**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
<b>or</b>	
<input type="checkbox"/>	Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy
<b>or</b>	
<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
<b>and</b>	
<input type="checkbox"/>	An initial response lasting at least 12 months was demonstrated
<b>and</b>	
<input type="checkbox"/>	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<sup>2</sup> 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<sup>2</sup> 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)

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

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

**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<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.

**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<sup>2</sup> 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

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<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 — 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<sup>2</sup> 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<sup>2</sup> 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.

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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<sup>2</sup> 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<sup>2</sup> every 8 weeks (maximum of 12 cycles)

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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<sup>2</sup>

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<sup>2</sup> 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<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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