Appendix to Notification Letter for rituximab and eltrombopag dated 20 February 2014

The notification letter which contains details of the decision to widen the restriction criteria for rituximab and eltrombopag can be found at: http://www.pharmac.health.nz/assets/notification-2014-02-20-rituximab-eltrombopag.pdf

Rituximab

The restriction criteria for rituximab in DHB hospitals (Part II of Section H) will be widened to include the following indications from 1 March 2014:

Cold haemagglutinin disease (CHAD)

Initiation - severe cold haemagglutinin disease (CHAD)
Haematologist
Limited to 4 weeks' treatment

Both:

1 Patient has cold haemagglutinin disease*; and

2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

Note: Indications marked with * are Unapproved Indications.

Continuation - severe cold haemagglutinin disease (CHAD)
Haematologist
Limited to 4 weeks' treatment

Either:

1 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

2 All of the following:

2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and

2.2 An initial response lasting at least 12 months was demonstrated; and

2.3 Patient now requires repeat treatment.

Note: Indications marked with * are Unapproved Indications.

Warm autoimmune haemolytic anaemia (warm AIHA)

Initiation - warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
Limited to 4 weeks' treatment

Both:

1 Patient has warm autoimmune haemolytic anaemia*; and

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2 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.

Note: Indications marked with * are Unapproved Indications.

Continuation - warm autoimmune haemolytic anaemia (warm AIHA)
Haematologist
Limited to 4 weeks' treatment

Either:

1 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

2 All of the following:

2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and

2.2 An initial response lasting at least 12 months was demonstrated; and

2.3 Patient now requires repeat treatment.

Note: Indications marked with * are Unapproved Indications.

Immune thrombocytopenic purpura (ITP)

Initiation – immune thrombocytopenic purpura (ITP)
Haematologist
Limited to 4 weeks' treatment

Both:

1 Either:

1.1. Patient has immune thrombocytopenic purpura* with a platelet count of ≤ 20,000 platelets per microlitre; or

1.2. Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and

2 Any of the following:

2.1. Treatment with steroids and splenectomy have been ineffective; or

2.2. Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or

2.3. Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).

Note: Indications marked with * are Unapproved Indications.

Continuation - immune thrombocytopenic purpura (ITP)
Haematologist
Limited to 4 weeks' treatment

Either:

1 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

2 All of the following:

2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and

2.2 An initial response lasting at least 12 months was demonstrated; and

2.3 Patient now requires repeat treatment.

Note: Indications marked with * are Unapproved Indications.

Thrombotic thrombocytopenic purpura (TTP)

Initiation – thrombotic thrombocytopenic purpura (TTP)

Haematologist
Limited to 4 weeks' treatment
Either:

1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or

2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.

Note: Indications marked with * are Unapproved Indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)

Haematologist

Limited to 4 weeks' treatment
All of the following:

1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and

2 An initial response lasting at least 12 months was demonstrated; and

3 Patient now requires repeat treatment.

Note: Indications marked with * are Unapproved Indications.

Pure red cell aplasia (PRCA)

Initiation – pure red cell aplasia (PRCA)
Haematologist
Limited to 6 weeks' treatment

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

Note: Indications marked with * are Unapproved Indications.

Continuation – pure red cell aplasia (PRCA)

Haematologist
Limited to 6 weeks' treatment

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.

ANCA associated vasculitis

Initiation - ANCA associated vasculitis
Rheumatologist or nephrologist
Limited to 4 weeks' treatment

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Either:
  2.1. Patient does not have MPO-ANCA positive vasculitis*; or
  2.2. Mycophenolate mofetil has not been effective in those patients who have MPO-ANCA positive vasculitis*; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks; and
4 Any of the following:
  4.1. Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve complete absence of disease after at least 3 months; or
  4.2. 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
  4.3. Cyclophosphamide and methotrexate are contraindicated; or
  4.4. Patient is a female of child-bearing potential; or
  4.5. Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are Unapproved Indications.

Continuation - ANCA associated vasculitis
Rheumatologist or nephrologist
Limited to 4 weeks' treatment

All of the following:

1. Patient has been diagnosed with ANCA associated vasculitis*; and
2. Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3. The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are Unapproved Indications.

Systemic lupus erythematosus (SLE)

Initiation - treatment refractory systemic lupus erythematosus (SLE)

Rheumatologist or nephrologist

All of the following:

1. The patient has severe, immediately life- or organ-threatening SLE*; and
2. The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
3. 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
4. Maximum of four 1000 mg infusions of rituximab.

Note: Indications marked with * are Unapproved Indications.

Continuation - treatment refractory systemic lupus erythematosus (SLE)

Rheumatologist or nephrologist

All of the following:

1. Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and
2. The disease has subsequently relapsed; and
3. Maximum of two 1000 mg infusions of rituximab.

Note: Indications marked with * are Unapproved Indications.

Antibody-mediated renal transplant rejection

Antibody-mediated renal transplant rejection

Nephrologist

Patient has been diagnosed with antibody-mediated renal transplant rejection*.

Note: Indications marked with * are Unapproved Indications.

ABO-incompatible renal transplant

ABO-incompatible renal transplant

Nephrologist

Patient is to undergo an ABO-incompatible renal transplant*.

Note: Indications marked with * are Unapproved Indications.

Eltrombopag

From 1 March 2014, the restriction criteria for eltrombopag in Section B and Part II of Section H will be amended as follows (additions in bold, deletions in strikethrough):

Section B

Initial application - (idiopathic thrombocytopenic purpura – post-splenectomy) only from a haematologist. Approvals valid for 6 weeks for applications meeting the following criteria:
All of the following:

1. Patient has had a splenectomy; and
2. Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
3. ~~Either~~ **Any of the following**:
   - 3.1. **Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding; or**
   - 3.2. Patient has a platelet count of ≤20,000 platelets per microlitre and has evidence of active bleeding; or
   - 3.3. Patient has a platelet count of ≤10,000 platelets per microlitre.

Initial application - (idiopathic thrombocytopenic purpura – preparation for splenectomy) only from a haematologist. Approvals valid for 6 weeks where the patient requires eltrombopag treatment as preparation for splenectomy.

Renewal– (idiopathic thrombocytopenic purpura – post-splenectomy) from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.
Note: Response to treatment is defined as a platelet count of >30,000 platelets per microlitre.

Part II of Section H

Initiation (idiopathic thrombocytopenic purpura - post-splenectomy)
Haematologist
Re-assessment required after 6 weeks
All of the following:

1 Patient has had a splenectomy; and
2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
3 ~~Either~~ **Any of the following**:
   - 3.1. **Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding; or**
   - 3.2. Patient has a platelet count of ≤ 20,000 platelets per microlitre and has evidence of active bleeding; or
   - 3.3. Patient has a platelet count of ≤ 10,000 platelets per microlitre.

Initiation - (idiopathic thrombocytopenic purpura - preparation for splenectomy)
Haematologist
Re-assessment required after 6 weeks
The patient requires eltrombopag treatment as preparation for splenectomy.

Continuation - (idiopathic thrombocytopenic purpura - post-splenectomy)
Haematologist
Re-assessment required after 12 months

The patient has obtained a response (see note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

Note: Response to treatment is defined as a platelet count of > 30,000 platelets per microlitre.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.