National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2024

I, Kelly Fisher, Delegate of the Minister for Health and Aged Care, make the following Determination.

Dated 27 August 2024

Kelly Fisher
Assistant Secretary, Immunisation Reform Branch, National Immunisation Division

Contents

1 Name

This instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2024*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 September 2024.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of this table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsections 9B(2) and (5) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Immunisation Program — Designated Vaccines) Determination 2014 (No.1)

1 After subsection 7(14)

Insert:

(15) For item 217A of Schedule 1, a designated vaccine mentioned in that item may be provided to a person who is at least 18 years of age and is considered at increased risk of herpes zoster in any of the following circumstances, noting that more than one circumstance may be applicable:

(a) has an underlying condition, including any of the following:

(i) acute haematological malignancies such as acute leukaemia or aggressive lymphomas;

(ii) chronic haematological malignancies, such as:

(A) myelodysplastic syndromes;

(B) chronic myeloproliferative disorders;

(C) lymphoproliferative malignancies;

(D) plasma cell dyscrasias which includes myeloproliferative neoplasms, chronic lymphocytic leukaemia, indolent non-Hodgkin lymphoma or multiple myeloma;

(iii) human immunodeficiency virus infection with CD4+ cell count < 200/μL;

(iv) inborn errors of immunity with ongoing functional deficits including:

(A) humoral e.g., X-linked agammaglobulinemia;

(B) combined defects, including severe combined immunodeficiency;

(C) phagocytic disorders, including chronic granulomatous disease; or

(D) other inborn errors of immunity except complement disorders, hereditary angioedema and IgA deficiency ;

(v) stage 5 kidney disease or on dialysis;

(b) malignancy, autoimmune or inflammatory conditions receiving immunomodulatory or immunosuppressive treatments, including any of the following:

(i) cellular therapies, whether received currently or within the previous 24 months, including:

(A) autologous haematopoietic stem cell transplant;

(B) allogeneic haematopoietic stem cell transplant, including ongoing graft vs host disease with immunosuppressive therapy, where a person is considered high risk beyond a 24 month period; or

(C) chimeric antigen receptor T-cell therapy;

(ii) B and T-cell targeted monoclonal antibody therapies, whether received currently or within the last 6 months, including any of the following:

(A) anti-CD20;

(B) anti B-cell activating factor;

(C) anti-CD52;

(D) anti-thymocyte globulin;

(iii) conventional chemotherapy for:

(A) treatment of haematological malignancy; or

(B) solid organ tumours, currently or within the last 6 months;

(iv) immunosuppressive therapy to prevent organ rejection prior to or following solid organ transplantation, currently or within the last 6 months;

(v) conventional immunosuppressive agents, currently or within the last 6 months, including any of the following:

(A) high dose methotrexate ≥20mg per week (oral and subcutaneous);

(B) azathioprine ≥3.0mg/kg/day;

(C) 6-mercaptopurine ≥1.5mg/kg/day;

(D) mycophenolate ≥1g/day;

(E) cyclophosphamide;

(F) systemic calcineurin inhibitors such as tacrolimus or cyclosporin;

(G) mTOR inhibitors;

(H) purine analogues such as cladribine;

(vi) biologic therapies, currently being received or that have been received in the last 6 months, not including lower risk biologics such as anti-integrins including natalizumab and vedolizumab, anti-IgE antibodies, anti-complement antibodies and lower risk interleukin (IL) inhibitors anti-IL17 antibodies, anti-IL 12/23 antibodies, anti-IL23 antibodies, and anti-IL31 antibodies, but including any of the following:

(A) tumour necrosis factor inhibitors;

(B) T-cell co-stimulation modulators such as Abatacept);

(C) soluble TNF receptors;

(D) type I interferon receptor inhibitors;

(E) proteasome inhibitors;

(F) IL inhibitors currently or within the last 6 months, including anti-IL1 antibodies, anti-IL4/13 antibodies, anti-IL5 antibodies, anti-IL6 antibodies, IL-6 receptor inhibitors;

(vii) immunomodulatory drugs including sphingosine-1-phosphate receptor modulators within the last 6 months;

(viii) oral small molecule targeted therapies, received currently or within the last 6 months including any of the following:

(A) bruton's tyrosine kinase inhibitors;

(B) janus kinase inhibitors;

(C) BCR-ABL inhibitors.

2 Part 1 of Schedule 1 (table item 103, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit "." at the end of (b), substitute:

; or

(c) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

3 Part 1 of Schedule 1 (table item 104, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit "Vaccine may be provided to a child who is about 2, 4 or 12 months old.", substitute:

Vaccine may be provided to:

(a) a child who is about 2, 4 or 12 months old; or

(b) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

4 Part 1 of Schedule 1 (table item 105, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit "Vaccine may be provided to a child who is about 12 months old.", substitute:

Vaccine may be provided to:

(a) to a child who is about 12 months old; or

(b) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have inadequate an clinical response or are intolerant to treatment with eculizumab or ravulizumab.

5 Part 1 of Schedule 1 (table items 106, 107 and 108, columns headed "Vaccine and the circumstances in which vaccine may be provided" , subheading "Circumstances")

After (b)(ii), insert:

; or

(c) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

6 Part 1 of Schedule 1 (table item 108A, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit "." at the end of (e), substitute:

; or

(f) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

7 Part 1 of Schedule 1 (table item 108B, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit "." at the end of (b), substitute:

; or

(c) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

8 Part 1 of Schedule 1 (table item 108B, column headed "Active ingredient and strength")

Omit "Each 0.5 mL reconstituted dose contains", substitute "Each 0.5 mL dose contains".

9 Part 1 of Schedule 1 (table item 108C, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances" after paragraph (d))

Omit all the words after paragraph (d), substitute:

(e) a person aged at least 12 months old undergoing eculizumab treatment; or

(f) a person who undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

10 Part 1 of Schedule 1 (table item 109, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances" after paragraph (b))

At the end of circumstance (b), insert:

; or

(c) a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

11 Part 1 of Schedule 1 (table item 110, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit all the words after "Vaccine may be provided:"; substitute:

(a) to a child who is about 2, 4 or 12 months old, but less than 24 months old; or

(b) in the circumstances set out in subsection 7(1); or

(c) to a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

12 Part 1 of Schedule 1 (table item 111, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit all the words after the subheading "Circumstances"; substitute:

Vaccine may be provided to:

(a) a child who is about 2, 4, 6 or 18 months old; or

(b) to a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

13 Part 1 of Schedule 1 (table item 112, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit all the words after the subheading "Circumstances"; substitute:

Vaccine may be provided:

(a) in the circumstances set out in subsection 7(2); or

(b) to a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

14 Part 1 of Schedule 1 (table item 114, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit all the words after the subheading "Circumstances"; substitute:

Vaccine may be provided:

(a) in the circumstances set out in subsection 7(13); or

(b) to a person who is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab.

15 Part 2 of Schedule 1 (table item 217A, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")

Omit all the words after paragraph (b), substitute:

(c) at least 18 years of age and is considered at increased risk of herpes zoster due to:

(i) an underlying condition set out in subsection 7(15); or

(ii) immunomodulatory or immunosuppressive treatments in the circumstances set out in subsection 7(15).