

## Proposals reviewed at prioritisation meetings

1 Jan 2020 to 31 Dec 2023

### 4<sup>th</sup> of March 2020

#### Proposals ranked within meeting

Cost-neutral or cost-saving:

- Cladribine – treatment of relapsing-remitting multiple sclerosis

Recommended for decline:

- Widening of access to multiple sclerosis treatments for the treatment of CIS

Options for Investment – new:

- Abiraterone acetate - hormone naïve and hormone sensitive metastatic prostate cancer
- Nusinersen – multiple proposals for spinal muscular atrophy (SMA)
  - Pre-symptomatic SMA only (genetic screening at birth)
  - Symptomatic SMA type I, II and III only
  - Combined pre-symptomatic SMA and symptomatic SMA I-IIIa
- Multiple Sclerosis (MS) treatments (Aubagio, Avonex, Betaferon, Copaxone, Gilenya, Tecfidera, Tysabri)- Amending stopping criteria to EDSS 6.5 (note recommendation for funding was amending stopping criteria to EDSS 6.0)
- Adalimumab - juvenile idiopathic arthritis (access widening)
- Etanercept - juvenile idiopathic arthritis (access widening)
- Sirolimus - widening access to include lymphovascular malformations

Options for Investment – reranked:

- Adrenaline auto-injector – Anaphylaxis
- Emicizumab – Haemophilia A with factor VIII inhibitors

#### Proposals ranked outside meeting

Tocilizumab, subcutaneous – Rheumatoid arthritis: Removed from OFI and placed under analysis

Options for Investment – new:

- Low protein foods - phenylketonuria (PKU)
- Valganciclovir – Widening access, extended use after lung transplant and methyl-prednisone

**3<sup>rd</sup> of June 2020**

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Ribociclib – Breast cancer, locally advanced/metastatic, HER2negative, HRpositive, first-line endocrine treatment
- Ribociclib – Breast cancer, locally advanced/metastatic, HER2negative, HRpositive, second-line endocrine treatment (not currently on OFI?)
- Adalimumab - Ulcerative Colitis, 1st line

Recommended for decline:

- Esketamine – treatment-resistant depression
- Influenza – influenza in patients with serious mental health conditions and addiction
- Cysteamine/mercaptamine (eye drops) - cystinosis
- Doxylamine - Use in nausea and vomiting
- Eplerenone – Heart failure: ejection  $\leq$  40%, diabetes or a risk of diabetes

Options for Investment – new:

- Tolvaptan - Polycystic chronic kidney disease
- Adalimumab, infliximab – Inflammatory bowel diseases - widening access (dose escalation)
- Sirolimus - Tuberous sclerosis (TSC) 2 years & older with refractory epilepsy and not an epilepsy surgery candidate
- Everolimus - Tuberous sclerosis (TSC) 2 years & older with refractory epilepsy and not an epilepsy surgery candidate
- Sirolimus - Angiomyolipoma associated with tuberous sclerosis complex
- Everolimus - Angiomyolipoma associated with tuberous sclerosis complex
- Vismodegib - Basal cell carcinoma, locally advanced or metastatic

Options for Investment – reranked:

- Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes
- TNF Inhibitors - Adalimumab - Undifferentiated spondyloarthritis
- Ibrutinib- relapsed/refractory mantle cell lymphoma
- Emicizumab- haemophilia A with factor VIII inhibitors
- TNF inhibitors – Infliximab – Inflammatory bowel disease- associated arthritis
- TNF inhibitors – Adalimumab – Inflammatory bowel disease- associated arthritis
- Nusinersen (Spinraza) - Presymptomatic individuals with spinal muscular atrophy
- Nusinersen - Spinal muscular atrophy Type 1, 2 and 3
- Abiraterone acetate- prostate cancer, metastatic, naïve/hormone sensitive
- Vedolizumab - Crohn's disease, 2nd line for primary non-responders to infliximab or adalimumab
- Vedolizumab - Ulcerative colitis, 2nd line, for primary and secondary non-responders to infliximab
- Adalimumab - Ulcerative colitis, moderately to severely active, 2nd line
- Ustekinumab - Severe Crohn's disease - second line
- Ustekinumab - Severe Crohn's disease - third line

- Meningococcal ACWY – children 1 year of age
- Meningococcal ACWY- Children 1 year of age plus 1 to 4 years with catchup (one year only)
- Meningococcal ACWY - Adolescents at 14 years of age
- Meningococcal ACWY- Adolescents 5 to 21 years with catchup (one year only), ongoing 14 years old
- Meningococcal ACWY- Adolescents 13 to 21 years with catchup (one year only), ongoing 14 year olds
- Meningococcal group B vaccine - Invasive meningococcal disease: Infant (2+1) - Infant Schedule (2+1 dosing)

Proposals ranked outside meeting

Options for investment – new:

- Bedaquiline - rifampicin-resistant and multi drug-resistant tuberculosis

**1<sup>st</sup> Sep 2020**

Proposals ranked within meeting

Cost-neutral or cost-saving:

- TOBI podhaler - Pseudomonas aeruginosa infection in CF
- Migalastat - Fabry disease (with amenable mutation)

Recommended for decline:

- Modafinil – excessive daytime sleepiness in OSA

Options for investment – new:

- Rituximab – Precursor B-cell Acute lymphoblastic leukaemia
- Rosuvastatin – Cholesterol control if intolerant to high dose atorvastatin (3rd line statin)
- Obinutuzumab - Non-Hodgkins lymphoma (rituximab refractory/relapsed)
- Ustekinumab – Adult patients with moderately to severely ulcerative colitis who have failed treatment with infliximab
- Sirolimus ointment – Facial angiofibromas secondary to tuberous sclerosis complex
- Pembrolizumab – Hodgkin lymphoma (bridge to transplant)

Options for investment – reranked:

- Brentuximab vedotin - Relapsed or refractory Hodgkin's lymphoma, ASCT ineligible patients
- Brentuximab vedotin - Relapsed or refractory Hodgkin's lymphoma after auto transplantation
- SGLT2 inhibitor - Type 2 diabetes mellitus with established cardiovascular disease or at high risk
- GLP1 agonist - Type 2 diabetes mellitus with established cardiovascular disease or at high risk
- Vedolizumab - Ulcerative colitis, 2nd line, for primary and secondary non-responders to infliximab
- Vedolizumab - Crohn's disease, 2nd line for primary and secondary non-responders to infliximab and/or adalimumab

Proposals ranked outside meeting

Options for investment – new:

- Budesonide CR 9mg – Ulcerative colitis
- Adjuvanted quadrivalent influenza vaccine (aQIV) - Influenza vaccination for people 65+ years of age

Options for investment – reranked:

- TNF Inhibitors – Adalimumab – Undifferentiated spondyloarthritis
- Adalimumab – Inflammatory bowel disease-associated arthritis
- Agalsidase alfa - Fabry disease (a-galactosidase A deficiency) by enzyme replacement therapy
- Low protein foods – PKU phenylketonuria
- Meningococcal B – infants

- Meningococcal B – high risk immunocompromised patients
- Meningococcal B – contacts of cases
- Everolimus for renal angiomyolipoma: Correct possible CUA range to (1-3)
- Denosumab – osteoporosis in patients with significant renal impairment
- Meningococcal B – entrants to close living environments and one year catch up (13-25 years)
- Meningococcal B – entrants to close living environments (13-25 years) no catchup

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

**1<sup>st</sup> of Dec 2020**

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Adjuvanted inactivated quadrivalent influenza vaccine - influenza vaccination for people aged 65 years and over
- Osimertinib – NSCLC (firstline)

Recommended for decline:

- Esketamine for MDSI with active suicidal ideation

Options for investment – new:

- Carfilzomib – relapsed or refractory multiple myeloma
- Daratumumab (in combination with bortezomib and dexamethasone) for relapsed or refractory multiple myeloma
- Gemtuzumab ozogamicin – For use in combination with daunorubicin and cytarabine for treatment of de novo acute myeloid leukaemia
- Midostaurin – Acute myeloid leukaemia (AML) - FLT3-mutation positive
- Vedolizumab – Ulcerative colitis, moderate to severe, 1st line
- Vedolizumab – Crohn's disease, severe, first line

Options for investment – reranked:

- Adalimumab – Crohn's disease, severe, rescue therapy
- Ustekinumab – Crohn's disease, severe, 2nd line after infliximab and/or adalimumab
- Ustekinumab – Ulcerative colitis, moderate to severe, 2nd line after infliximab

Proposals ranked outside meeting

Options for investment – new:

- Rituximab - Membranous nephropathy

Options for investment – reranked:

- Adalimumab – Ulcerative colitis, moderate to severe, 2nd line after infliximab
- Adalimumab – Crohn's disease - widening access (dose escalation)
- Infliximab – Crohn's disease and ulcerative colitis - widening access (dose escalation)
- Nusinersen – Spinal muscular atrophy Type I, II and III
- Nusinersen – Presymptomatic individuals with spinal muscular atrophy
- Secukinumab – Psoriatic arthritis, 1st biologic line
- Secukinumab – Psoriatic arthritis, 2nd biologic line
- Secukinumab – Ankylosing spondylitis, 2nd biologic line
- Sodium picosulfate liquid – Constipation in children
- Ustekinumab – Crohn's disease, severe, 3rd line after infliximab and adalimumab
- Vedolizumab – Crohn's disease, severe, 2nd line after infliximab and/or adalimumab
- Vedolizumab – Ulcerative colitis, moderate to severe, 2nd line after infliximab

**2<sup>nd</sup> of March 2021**

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Everolimus - Tuberous sclerosis (TSC) 2 years & older with refractory epilepsy
- Everolimus - Angiomyolipoma associated with tuberous sclerosis complex

Recommended for decline:

- Quinacrine – systemic lupus erythematosus (SLE)
- Esketamine – major depressive disorder with active suicidal ideation with intent (MDSI)

Options for investment – new:

- Mepolizumab – eosinophilic asthma, widening access (lower blood eosinophil count to 300 cells/ $\mu$ L, remove ACT requirement from access criteria, and the combination)
- Ibrutinib – CLL, relapsed post venetoclax-containing regimens
- Durvalumab – unresectable, locally advanced NSCLC

Options for investment – reranked:

- Peptide receptor radionuclide therapy – neuroendocrine tumours
- Octreotide LAR (somatostatin analogue) - Acromegaly pre-operatively in preparation for pituitary surgery
- Vedolizumab – ulcerative colitis, moderate to severe, 1st line and 2nd line
- Vedolizumab – Crohn's disease, severe, 1st line and 2nd line
- Infliximab – inflammatory bowel disease-associated arthritis

Proposals ranked outside meeting

Options for investment – new:

- Lanreotide acetate - Gastroenteropancreatic neuroendocrine tumours, non-functional
- Adalimumab – ulcerative colitis, moderate to severe, 1st line
- Adalimumab – undifferentiated spondyloarthritis, 2nd line

Options for investment – reranked:

- Ibrutinib – CLL with 17p deletion or TP53, alternative to venetoclax
- Nivolumab – metastatic renal cell carcinoma, 2nd line
- Axitinib – metastatic renal cell carcinoma, 2nd line
- Budesonide controlled-release 9mg – Ulcerative colitis
- Adalimumab – undifferentiated spondyloarthritis, 1st line
- Adalimumab – inflammatory bowel disease-associated arthritis
- Tolvaptan – polycystic chronic kidney disease

**1<sup>st</sup> of June 2021**

Proposals ranked within meeting

Options for investment – new:

- Trastuzumab emtansine (T-DM1) - early breast cancer
- Azacitidine - widening access (therapy-related MDS)
- Azacitidine – widening access (AML blast count  $\geq 30\%$ )
- Azacitidine – widening access (AML blast count  $\geq 30\%$  and therapy-related MDS)
- Risdiplam – SMA, type 1
- Budesonide/formoterol (STAT dispensing) – asthma
- Lenvatinib/everolimus - metastatic renal cell carcinoma
- MS treatments – widening access (2017 McDonald criteria)
- Brentuximab vedotin - CD30-positive systemic anaplastic large-cell lymphoma
- Brentuximab vedotin – Relapsed/refractory Hodgkin's lymphoma (HL) and systemic anaplastic large-cell lymphoma (ALCL)
- Adalimumab/etanercept – Rheumatoid arthritis (remove SA criteria relating to CRP)
- Adalimumab/etanercept – Rheumatoid arthritis (amendment to SA criteria to reduce joint count from 20 to 15)
- Adalimumab/etanercept – Rheumatoid arthritis (reduce number of prior DMARDs from 3 to 2)

Options for investment – reranked:

- Aprepitant for post-operative nausea and vomiting
- Adalimumab - Ulcerative colitis, moderately to severely active, 1st line
- Adalimumab - Ulcerative colitis, moderate to severe, 2nd line after infliximab
- Adalimumab - Crohn's disease - widening access (dose escalation)
- Adalimumab - Crohn's disease, severe, rescue therapy
- Adalimumab - Inflammatory bowel disease-associated arthritis
- Adalimumab - Undifferentiated spondyloarthritis, 1st line
- Adalimumab - Undifferentiated spondyloarthritis, 2nd line (after etanercept)
- Brentuximab vedotin – relapsed or refractory Hodgkin's lymphoma, ASCT ineligible patients
- Brentuximab vedotin – relapsed or refractory Hodgkin's lymphoma after auto transplantation

Proposals ranked outside meeting

Cost-neutral or cost-saving:

- Rifampicin / Isoniazid / Pyrazinamide / Ethambutol - fixed dose combinations – Tuberculosis
- Fluticasone furoate with umeclidinium bromide and vilanterol trifenate – COPD

Recommended for decline:

- Ibrutinib – Chronic lymphocytic leukaemia, relapsed / refractory Del 11q



- Atezolizumab – non-small cell lung cancer, metastatic, in combination with chemotherapy, first-line
- Pembrolizumab - First-line treatment of recurrent or metastatic head and neck cancer
- Lactic acid and thymol gel - Bacterial vaginosis
- Oseltamivir - treatment and prophylaxis of influenza during influenza outbreaks in long-term care facilities
- Albendazole – Giardiasis
- Oral Feed 1.25 kcal/ml - Cubitan - Pressure ulcers
- Ceftolozane with tazobactam - Significant infections due to multi-resistant aerobic
- Pneumococcal vaccine - Pneumovax 23 - Individuals with untreated chronic lymphocytic leukaemia/small lymphocytic lymphoma (CLL/SLL).

Options for investment – new:

- Rituximab – pemphigus (all types)
- Zoledronic acid – prevention of bone loss post-spinal cord injury

**18<sup>th</sup> of June 2021**

Proposals ranked within meeting

Recommended for decline:

- Denosumab - Hypercalcemia (associated with malignant bone disease) in patients with renal impairment
- Bevacizumab - metastatic colorectal cancer – first and second-line treatment
- Everolimus - Breast cancer, advanced, hormone receptor positive, HER-2 negative

Proposals ranked outside meeting

Options for investment – new:

- Zoledronic acid - Treatment of moderate to severe hypercalcaemia
- Benralizumab – Alternate line treatment for eosinophilic asthma

Options for investment – reranked:

- Meningococcal A, C, Y And W-135 Vaccine, Meningococcal C Conjugated Vaccine - Children 1 year of age
- Meningococcal A, C, Y And W-135 Vaccine, Meningococcal C Conjugated Vaccine - Children 1 year of age plus 1 to 4 years with catchup (one year only)
- Meningococcal A, C, Y And W-135 Vaccine, Meningococcal C Conjugated Vaccine - Adolescents at 14 years of age
- Meningococcal A, C, Y And W-135 Vaccine, Meningococcal C Conjugated Vaccine - Adolescents 5 to 21 years with catchup (one year only), ongoing 14 years old
- Meningococcal A, C, Y And W-135 Vaccine, Meningococcal C Conjugated Vaccine - Adolescents 13 to 21 years with catchup (one year only), ongoing 14 year olds
- Gemtuzumab ozogamicin - For use in combination with daunorubicin and cytarabine for treatment of de novo acute myeloid leukaemia

8<sup>th</sup> of Sep 2021

Proposals ranked within meeting

Recommended for decline:

- Adalimumab/etanercept - Rheumatoid arthritis - amendment to SA criteria to include patient-reported outcomes
- Lenalidomide - in combination with dexamethasone for the first-line treatment of transplant eligible patients with multiple myeloma
- Linagliptin - Diabetes - type 2
- Dapagliflozin - Diabetes - type 2
- Liraglutide – Diabetes – type 2
- Canagliflozin – Diabetes – type 2
- Levofloxacin - Helicobacter pylori - second line use
- Peptide Receptor Radionuclide Therapy - Neuroendocrine tumours
- Pegylated liposomal doxorubicin - Advanced epithelial ovarian cancer (3rd-line treatment) - platinum resistant
- Insulin pump (including consumables) - Diabetes during pregnancy
- Lidocaine [lignocaine] with adrenaline and tetracaine (4%; 0.1%; 0.5%) - Wound repair for children
- Lidocaine [Lignocaine] With Prilocaine - Widening community access for adults
- Lidocaine [lignocaine] with adrenaline and tetracaine (4%; 0.1%; 0.5%) - Wound repair (not restricted by age)
- Topical non-steroidal anti-inflammatory drugs (NSAIDs) - Diclofenac, Ibuprofen, Ketoprofen, Piroxicam – Osteoarthritis
- Levodopa / Carbidopa intestinal gel - Advanced Parkinson's with severe motor fluctuations despite optimised alternative treatment
- Lacosamide - Epilepsy, move up to 5th line
- Methoxyflurane - Pain relief

Options for investment – new:

- Lenvatinib mesilate - First-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
- Lenvatinib mesilate - progressive, locally advanced or metastatic, radioactive iodine (RAI) refractory differentiated thyroid cancer (DTC)
- Entrectinib - Non-small cell lung cancer (NSCLC) - adult patients with ROS1-positive, locally advanced or metastatic
- Crizotinib - Non-small cell lung cancer, locally advanced or metastatic, ROS1 gene translocation
- Cinacalcet - Primary hyperparathyroidism
- Zoledronic acid – open listing
- Risdiplam – SMA, types 1-3
- Venetoclax - in combination with either azacitidine (based on widened access to azacitidine) or low dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia ineligible for intensive induction chemotherapy
- Venetoclax - in combination with either azacitidine or low dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia ineligible for intensive induction chemotherapy

- Pembrolizumab - Relapsed or refractory Hodgkin's lymphoma after auto transplantation
- Pembrolizumab - Relapsed or refractory Hodgkin's lymphoma, ASCT ineligible patients
- Pembrolizumab - Relapsed/refractory Hodgkin's lymphoma after two or more lines of chemotherapy for patients who are either ineligible for, or relapsed following, an autologous stem cell transplant
- Denosumab - osteoporosis - access widening to those contraindicated to bisphosphonates

Options for investment – reranked:

- Nusinersen - Spinal muscular atrophy Type I, II and III
- Brentuximab vedotin - Relapsed or refractory Hodgkin's lymphoma, ASCT ineligible patients
- Denosumab - osteoporosis - access widening to those contraindicated or intolerant to bisphosphonates
- Mepolizumab – Widened access (ACT and >300 cells/ul eosinophil count criteria)
- Budesonide controlled-release 9 mg - Mild to moderately active ulcerative colitis
- Lenvatinib/everolimus – metastatic renal cell carcinoma

#### Proposals ranked outside meeting

Miscellaneous:

- Clindamycin vaginal cream - Bacterial vaginosis and desquamative inflammatory vaginitis: No currently available product – removed from OFI and placed on the Under Assessment list.
- Budesonide, oral viscous nebules - Eosinophilic oesophagitis unresponsive to fluticasone in adults: No currently available product – removed from OFI and placed on the Under Assessment list.
- Budesonide, oral viscous nebules - Eosinophilic oesophagitis unresponsive to fluticasone in children: No currently available product – removed from OFI and placed on the Under Assessment list.
- Eculizumab - Paroxysmal nocturnal haemoglobinuria (PNH): Removed from OFI and decline decision reinstated.

27<sup>th</sup> of Sep 2021

Proposals ranked within meeting

Options for investment – new:

- Elexacaftor/tezacaftor/ivacaftor and ivacaftor (ELX/TEZ/IVA) - cystic fibrosis patients aged 6 years and older with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

Options for investment – reranked:

- Nusinersen - Presymptomatic individuals with spinal muscular atrophy

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**1<sup>st</sup> of Dec 2021**

Proposals ranked within meeting

Options for investment – new:

- Alirocumab – prevention of CV events in people with heterozygous familial hypercholesterolaemia (HeFH)
- Alirocumab – hypercholesterolaemia in people with diabetes and acute coronary syndrome (ACS)
- Carfilzomib – (once-weekly) for the second-line treatment of relapsed or refractory multiple myeloma
- Daratumumab – In combination with bortezomib and dexamethasone (DvD) for the treatment of patients with multiple myeloma who have received one prior line of myeloma therapy (1PL).
- Pomalidomide – (in combination with bortezomib and dexamethasone, as PVD or in combination with dexamethasone if bortezomib intolerant or contraindicated) for the second-line treatment of relapsed or refractory multiple myeloma
- Risankizumab – Moderate to severe plaque psoriasis – first line biologic
- Risankizumab – Moderate to severe plaque psoriasis - second line biologic

Options for investment – reranked:

- Daratumumab (in combination with bortezomib & dexamethasone) – relapsed or refractory myeloma

Proposals ranked outside meeting

Recommended for decline:

- Adalimumab/etanercept – Rheumatoid arthritis - amendment to SA criteria to include patient-reported outcomes
- Lenalidomide – in combination with dexamethasone for the first-line treatment of transplant eligible patients with multiple myeloma

Options for investment – new:

- Cinacalcet Hcl - Tertiary hyperparathyroidism
- Cinacalcet Hcl – Secondary hyperparathyroidism
- Benralizumab - Severe eosinophilic asthma - Widened access (ACT and >300 cells/ul eosinophil count criteria)
- Olaparib - Ovarian, fallopian tube or primary peritoneal cancer, newly diagnosed, BRCA-mutated, platinum sensitive – maintenance

Options for investment – reranked:

- Mepolizumab - Widening access (>300 cell/uL and ACT removal)
- Trastuzumab emtansine - Adjuvant treatment of patients with HER2- positive early breast cancer who have residual disease after pre-operative systemic treatment that included HER2-targeted therapy.
- Obinutuzumab - Indolent Non-Hodgkins lymphoma (relapsed after or refractory to rituximab)

**2<sup>nd</sup> of March 2022**

Proposals ranked within meeting

Options for investment – new:

- Ocrelizumab - Primary Progressive Multiple Sclerosis
- Progesterone – Menopause
- Progesterone – Open listing
- Progesterone – Recurring early pregnancy loss (3 or more) with pre-vaginal bleeding
- Dexcom G6 - indicated for the management of diabetes in persons aged 2 years and older
- Atezolizumab - Hepatocellular carcinoma (HCC), unresectable, in combination with bevacizumab, first line
- Apalutamide – Prostate cancer, non-metastatic, castration-resistant, high risk
- Emicizumab - Haemophilia A without FVIII inhibitors.
- Elexacaftor/tezacaftor/ivacaftor and ivacaftor (ELX/TEZ/IVA) - For treatment of cystic fibrosis patients aged 12 years and older with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

Options for investment – reranked:

- Multiple Sclerosis (MS) Treatments - Widen access to include patients who meet the 2017 McDonald criteria
- Alirocumab - hypercholesterolaemia in people with diabetes and acute coronary syndrome (ACS)
- Freestyle Libre Flash Glucose Monitoring System - Type 1 diabetes

Proposals ranked outside meeting

Nil.

**28<sup>th</sup> of April 2022**

Proposals ranked within meeting

Options for investment – new:

- Cinacalcet Hcl – Hyperparathyroidism (all types)
- Emtricitabine with tenofovir disoproxil - Widening Access (PrEP) - removal of Restrictions - HIV pre-exposure prophylaxis

Options for investment – reranked:

- Ocrelizumab - Primary Progressive Multiple Sclerosis
- Multiple Sclerosis (MS) Treatments - Widen access to include patients who meet the 2017 McDonald criteria
- Progesterone – Menopause
- Progesterone – Open listing
- Progesterone – Recurring early pregnancy loss (3 or more) with pre-vaginal bleeding
- Venetoclax proposals for newly diagnosed AML ineligible for intensive induction chemotherapy
  - Venetoclax - In combination with either azacitidine (based on widened access to azacitidine) or low dose cytarabine, for the treatment of newly diagnosed AML ineligible for intensive induction chemotherapy
  - Venetoclax - In combination with either azacitidine or low dose cytarabine, for the treatment of newly diagnosed AML ineligible for intensive induction chemotherapy
- Azacitidine - Widening access proposals
  - Azacitidine - Widening access (therapy-related MDS)
  - Azacitidine - Widening access (AML blast count >30% and therapy-related MDS)
  - Azacitidine - Widening access (AML blast count >30%)

Proposals ranked outside meeting

Nil.



**1<sup>st</sup> of June 2022**

Proposals ranked within meeting

Options for investment – new:

- Influenza Vaccine - influenza in patients with serious mental health conditions and addiction (schizophrenia/psychotic disorders, major depression and bipolar)
- Influenza Vaccine - influenza in patients with serious mental health conditions and addiction (schizophrenia/psychotic disorders, major depression, bipolar and people accessing secondary and tertiary mental health disorders)
- Vedolizumab - Crohn's disease and ulcerative colitis, 1st line biologic
- Vedolizumab - Crohn's disease and ulcerative colitis, 2nd line biologic
- Ustekinumab - Crohn's disease and ulcerative colitis, 2nd line biologic
- Ustekinumab - Crohn's disease and ulcerative colitis, 3rd line biologic
- Letemovir - cytomegalovirus infection prophylaxis (stem cell transplant patients)

Options for investment – reranked:

- Atezolizumab – in combination with bevacizumab for unresectable hepatocellular carcinoma
- Abiraterone Acetate – Prostate Cancer, metastatic, hormone naive/hormone sensitive prostate cancer
- Apalutamide – Prostate cancer, non-metastatic, castration-resistant, high risk
- Nusinersen (Spinraza) – Presymptomatic individuals with spinal muscular atrophy
- Nusinersen – Combined presymptomatic SMA and symptomatic SMA I-IIIa
- Nusinersen – Spinal muscular atrophy Type I, II and III
- Risdiplam – The treatment of spinal muscular atrophy (SMA), including Types 1-3
- Elexacaftor/tezacaftor/ivacaftor and ivacaftor (ELX/TEZ/IVA) – For treatment of cystic fibrosis patients aged 6 years and older with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- Elexacaftor/tezacaftor/ivacaftor and ivacaftor (ELX/TEZ/IVA) – For treatment of cystic fibrosis patients aged 12 years and older with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

Proposals ranked outside meeting

Recommended for decline:

- Pembrolizumab - in combination with chemotherapy for those with recurrent or metastatic head and neck squamous cell carcinoma irrespective of Combined Positive Score (ie. an all-comers population)

Options for investment – new:

- Selenium and copper chloride - Patient is admitted to hospital with burns

Options for investment – reranked:

- Emtricitabine with tenofovir disoproxil - HIV Pre-Exposure Prophylaxis (PrEP) – Widening Access
- Emtricitabine with tenofovir disoproxil - Post-Exposure Prophylaxis following non-occupational exposure to HIV (nPEP) – Widening Access

- Budesonide/Formoterol (Dry Powder Inhaler) - dispensing in greater quantities than one (STAT dispensing) for asthma

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

21<sup>st</sup> of July 2022

Proposals ranked within meeting

Options for investment – reranked:

- Adrenaline auto-injector - Treatment of anaphylaxis; have had an anaphylactic reaction or are at high risk of reaction
- Nusinersen - Combined presymptomatic SMA and symptomatic SMA I-IIIa

Proposals ranked outside meeting

Options for investment – reranked:

- Obinutuzumab - Indolent Non-Hodgkin's lymphoma (relapsed after or refractory to rituximab)

7<sup>th</sup> of Sep 2022

Proposals ranked within meeting

Options for investment – new:

- Recombinant Zoster Vaccine - People over 65 years of age who require a shingrix catch-up at least 5 years post Zostavax
- Recombinant Zoster Vaccine - Vaccination for people at 50 years of age and a catch-up program for people 51 to 64 years, for the prevention of herpes zoster and post-herpetic neuralgia
- Lenalidomide - in combination with bortezomib and dexamethasone for the first-line treatment of transplant ineligible patients with multiple myeloma
- Lenalidomide - Multiple myeloma, first-line treatment, ASCT-eligible (induction) and ASCT-ineligible
- Upadacitinib - Moderate to severe atopic dermatitis
- Nab-paclitaxel - Metastatic breast cancer
- Nab-paclitaxel - Metastatic breast cancer contraindicated or intolerant to taxane chemotherapy
- Niraparib - First-line maintenance treatment of advanced, high-grade, platinum sensitive ovarian, fallopian tube or primary peritoneal cancer
- Niraparib - Second-line maintenance treatment of advanced, high-grade, platinum sensitive ovarian, fallopian tube or primary peritoneal cancer
- Ring pessary - Treatment for pelvic prolapse - vaginal or rectal in women

Options for investment – reranked:

- Non-latex condoms - Sexually transmitted infection (STI) prevention and contraception in patients with latex allergies
- Lubricant, non-irritant, water-based, single use - Sexual health
- Female/internal condoms - Sexually transmitted infection (STI) prevention and contraception
- Daratumumab – In combination with bortezomib and dexamethasone (DVd) for the treatment of patients with multiple myeloma who have received one prior line of myeloma therapy (1PL).
- ELX/TEZ/IVA - For treatment of cystic fibrosis patients aged 6 years and older with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- Nusinersen - Combined presymptomatic SMA and symptomatic SMA I-IIIa

Proposals ranked outside meeting

Options for investment – new:

- $\beta$ -hCG low-sensitivity urine test kit - Confirmation of termination of pregnancy
- Rituximab - IgG4 disease

7<sup>th</sup> of Dec 2022

Proposals ranked within meeting

Options for investment – new:

- Osimertinib - first-line treatment of patients with locally advanced or metastatic EGFRm NSCLC
- Osimertinib - Non-small cell lung cancer, locally advanced or metastatic, EGFR T790M positive, second line
- Eplerenone – Resistant hypertension; intolerant of spironolactone
- Eplerenone – Primary aldosteronism; intolerant of spironolactone
- Influenza vaccine - Options for widened access – Māori and Pacific people over 50 years of age
- Influenza vaccine - Options for widened access - Open listing
- Influenza vaccine - Options for widened access - People over 50 years of age
- Influenza vaccine - Options for widened access - Children up to 18 years of age
- Risdiplam – Combined pre-symptomatic spinal muscular atrophy (SMA) and symptomatic SMA types 1-3

Options for investment – reranked:

- Pomalidomide - (in combination with bortezomib and dexamethasone, as PVD) for the second-line treatment of relapsed or refractory multiple myeloma

Proposals ranked outside meeting

Cost-neutral or cost-saving:

- Paracetamol 1000 mg with ibuprofen 300 mg – 100 ml solution for infusion
- Adjuvanted Influenza Vaccine (Fluad Quad) – People aged 65 years

Recommended for decline:

- Bevacizumab – Second-line treatment of high-risk advanced ovarian cancer
- Rituximab biosimilar (Truxima)

Options for investment – new:

- Nab-paclitaxel – Metastatic breast cancer - following grade 3+ hypersensitivity reaction on paclitaxel

Options for investment – reranked:

- Atezolizumab – Hepatocellular carcinoma (HCC), unresectable, in combination with bevacizumab, first line
- Niraparib – Second-line maintenance treatment of advanced, high-grade, platinum sensitive ovarian, fallopian tube or primary peritoneal cancer
- Niraparib – First-line maintenance treatment of advanced, high-grade, platinum sensitive ovarian, fallopian tube or primary peritoneal cancer
- Ring pessary – Treatment for pelvic prolapse - vaginal or rectal in women
- Entrectinib – Non-small cell lung cancer (NSCLC) - adult patients with ROS1-positive, locally advanced or metastatic

- Letermovir – Cytomegalovirus prophylaxis in seropositive allogeneic haematopoietic stem cell transplant patients

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

25<sup>th</sup> of Jan 2023

Proposals ranked within meeting

Recommended for decline:

- Capsaicin 0.075% cream - Cannabinoid hyperemesis syndrome
- Sirolimus ointment – Facial angiofibromas secondary to tuberous sclerosis complex

Options for investment – new:

- Buprenorphine injection (Buvidal) – Opioid dependence, maintenance treatment
- Buprenorphine modified release solution for injection (Sublocade) - Opioid dependence, maintenance treatment
- Trastuzumab - Gastric cancer, locally advanced or metastatic, HER2 positive
- Budesonide orodispersible tablets - Eosinophilic oesophagitis, 2nd line after fluticasone

Options for investment – reranked:

- Ciclosporin eye preparation - Severe keratoconjunctivitis sicca, severe atopic keratoconjunctivitis and severe vernal keratoconjunctivitis

Proposals ranked outside meeting

Nil.

**8<sup>th</sup> of March 2023**

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Adalimumab (Humira) - Citrate free formulation

Options for investment – new:

- Inotuzumab – Acute lymphoblastic leukaemia (ALL), eligible and ineligible for transplant, relapsed/refractory CD22-positive, adults
- Inotuzumab – Acute lymphoblastic leukaemia (ALL), bridge to transplant, relapsed/refractory CD22-positive, adults
- Aripiprazole depot injection - People with schizophrenia at high risk of metabolic syndrome or have poor adherence to oral atypical antipsychotics
- Pembrolizumab with or without chemotherapy – Head and neck squamous cell carcinoma with a Combined Positive Score (CPS) >1, first-line
- Pembrolizumab with chemotherapy – Head and neck squamous cell carcinoma with a Combined Positive Score (CPS) >1, first-line
- Continuous glucose monitors - Type 1 diabetes

Options for investment – reranked:

- Lenvatinib – First-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
- Lenvatinib – Renal cell carcinoma, metastatic, clear cell, second-line
- Lenvatinib – For the treatment of progressive, locally advanced or metastatic, radioactive iodine (RAI) refractory differentiated thyroid cancer (DTC)

Proposals ranked outside meeting

Nil.



26<sup>th</sup> of April 2023

Proposals ranked within meeting

Options for investment – new:

- PCV13 – Prevention of IPD, supplemental dose for individuals ages 12 to 59 months

Proposals ranked outside meeting

Nil.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

6<sup>th</sup> of June 2023

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Riboflavin – Perioperative use (cystoscopy)
- Obinutuzumab – Follicular lymphoma, 1st line

Recommended for decline:

- Tacrolimus suppository - Rectal inflammation due to inflammatory bowel disease
- Whole Thyroid Extract, Normal Release T3 and Extended Release T3 – Hypothyroidism
- Levothyroxine oral liquid - Congenital hypothyroidism
- Budesonide, oral viscous nebules- Eosinophilic oesophagitis unresponsive to fluticasone in children
- Budesonide, oral viscous nebules- Eosinophilic oesophagitis unresponsive to fluticasone in adults
- Denosumab - Osteoporosis, removing definition of contraindicated to zoledronic acid
- Exenatide - Type 2 diabetes, with established cardiovascular disease
- Lixisenatide - Type 2 diabetes, with established cardiovascular disease
- Peginterferon alfa-2a - Myeloproliferative neoplasms
- Sapropterin - Hyperphenylalaninaemia due to PKU in non-pregnant PKU patients
- Multivitamins (Fruit-Vits and Phlexy-Vits)- Ketogenic dietary treatment for children with epilepsy
- Esketamine - Treatment-resistant depression

Options for investment – new:

- Bevacizumab – Ovarian cancer, advanced stage, 1L

Options for investment – reranked:

- Venetoclax (w widened access to azacitidine or low dose cytarabine) – acute myeloid leukaemia, newly diagnosed, ineligible for intensive chemotherapy
- Letermovir – Cytomegalovirus infection prophylaxis, stem cell transplant patients
- Pembrolizumab with or without chemotherapy – Head and neck squamous cell carcinoma with a Combined Positive Score (CPS) >1, first-line
- Pembrolizumab with chemotherapy– head and neck squamous cell carcinoma with a Combined Positive Score (CPS) >1, first-line
- Lenvatinib and everolimus - Renal cell carcinoma, metastatic, clear cell, 2nd line

Proposals ranked outside meeting

Nil.

6<sup>th</sup> of Sep 2023

Proposals ranked within meeting

Cost-neutral or cost-saving:

- Desogestrel – Contraception
- Abiraterone (Yonsa) - Prostate cancer, same indications as for originator
- Amino Acid plus vitamins and minerals - PKU Anamix 1st Spoon - Phenylketonuria (PKU)
- MSUD LOPHLEX POWDER - Maple Syrup Urine Disease
- TYR LOPHLEX POWDER - For use from 3 years of age and adults for the dietary management of Tyrosinaemia (TYR)
- HCU LOPHLEX POWDER – Homocystinuria

Recommended for decline:

- Fluticasone with salmeterol, high dose - Asthma and chronic obstructive pulmonary disease
- Fluticasone with Vilanterol, 200/25, high dose, severe asthma – Asthma
- Naltrexone hydrochloride - Removal of Special Authority
- Fosfomycin - Extended spectrum beta lactamase infections
- Insujet - Insulin administration
- Mirabegron - Open listing
- Mirabegron - Overactive bladder, 2nd line

Options for investment – new:

- Palivizumab - Extension of funding for RSV
- Zonisamide – Focal epilepsy, treatment refractory
- Zonisamide – Developmental and epileptic encephalopathies
- Ripretinib – Gastrointestinal stromal tumour (GIST)
- Recombinant Zoster Vaccine (Shingrix) - Prevention of herpes zoster infection, Māori and Pacific aged 60 – 64 Shingrix
- Guselkumab – Moderate-to-severe plaque psoriasis, first line biologic
- Guselkumab – Moderate-to-severe plaque psoriasis, second line biologic
- Currently funded biologics for psoriasis – Widened access to include flexural and genital psoriasis
- Sirolimus (Rapamycin) - Facial angiofibromas associated with Tuberous Sclerosis Complex
- Daratumumab – 2L subcutaneous + 4L infusion

Options for investment – reranked:

- Daratumumab subcutaneous (with bortezomib and dexamethasone) – Multiple myeloma, received one prior line of myeloma therapy (1PL).
- Pembrolizumab – Hodgkin's lymphoma
- Pneumococcal vaccine (PCV-13) - Prevention of invasive pneumococcal disease, individuals aged 12 to 59 months supplemental dose.
- Bevacizumab – Advanced ovarian, fallopian tube and peritoneal cancer
- Lenvatinib - Thyroid cancer, locally advanced or metastatic, differentiated, refractory to radioactive iodine

### Proposals ranked outside meeting

#### Cost-neutral or cost-saving:

- Lisdexamfetamine – Attention Deficit Hyperactivity Disorder (ADHD)
- Niraparib – Ovarian, fallopian tube and peritoneal cancer, BRCA-mutated, 1st line maintenance
- Niraparib – Ovarian, fallopian tube and peritoneal cancer, BRCA-mutated, 2nd line maintenance

#### Recommended for decline:

- Fexofenadine hydrochloride – Urticaria, children aged 6 months to 2 years
- Morphine sulphate (5mg / 5mL pre-filled syringes) - Acute pain
- Rituximab – Treatment of people with Class IV(a) lupus nephritis as part of the induction phase of therapy
- Octreotide LAR - Polycystic liver disease
- Clodronate – Osteoradionecrosis
- Vancomycin (5g vials) – Infected arthroplasty
- Moxifloxacin ophthalmic – Prophylaxis of post-op endophthalmitis
- Latex oral dams - Prevention of sexually transmitted infections
- Clindamycin vaginal cream - Bacterial vaginosis and desquamative inflammatory vaginitis
- D-mannose - Cystitis, uncomplicated during pregnancy or associated neurogenic bladder
- Elemental formula – Alfare - Cow's milk protein allergy, food intolerance and hypersensitivity

#### Options for investment – new:

- Denosumab – Hypercalcemia in people with malignant bone disease and renal impairment, second line
- Fosfomycin – Urinary Tract Infection

#### Options for investment – reranked:

- Denosumab – Osteoporosis, contraindicated to bisphosphonates
- Low protein foods – Phenylketonuria (PKU)
- Lenvatinib with everolimus – Renal cell carcinoma, metastatic, clear cell, 2nd line
- Eplerenone – Primary aldosteronism, intolerant to spironolactone
- Influenza vaccine – Prevention of influenza, people aged 0-18
- Influenza vaccine – Prevention of influenza, open listing
- Influenza vaccine – Prevention of influenza, people aged 50-64

**5<sup>th</sup> of Dec 2023**

**Proposals ranked within meeting**

**Cost-neutral or cost-saving:**

- Posaconazole - Prophylaxis of invasive fungal infections in people with high risk malignancies, lung and liver transplant recipients
- Voriconazole - Prophylaxis of invasive fungal infections in people with high risk malignancies, lung and liver transplant recipients
- Ofatumumab – Relapsing-remitting multiple sclerosis (RRMS)

**Recommended for decline:**

- Aprepitant – Nausea and vomiting associated with moderately emetogenic chemotherapy.

**Options for investment – new:**

- Teduglutide – Short bowel syndrome, with intestinal failure
- Atezolizumab – Extensive-stage small cell lung cancer
- Perampanel – Focal epilepsy
- Rufinamide – Developmental and epileptic encephalopathies
- Trastuzumab deruxtecan – Breast cancer, metastatic, HER2-positive
- Ustekinumab – Plaque psoriasis, moderate to severe, first-line biologic
- Ustekinumab – Plaque psoriasis, moderate to severe, second-line biologic
- Somatropin – Prader-Willi syndrome, widened access for adults and adolescents
- Somatropin – Short children born small for gestational age
- Somatropin – Short stature due to chronic renal insufficiency
- Empagliflozin – Heart failure, with reduced ejection fraction
- Darolutamide – Non-metastatic castration resistant prostate cancer, at high risk of metastasis
- Ferric carboxymaltose – Iron-deficiency anaemia

**Options for investment – reranked:**

- Influenza vaccine – Māori and Pacific adults, 50-64 years of age
- Denosumab – Osteoporosis, contraindicated to or unable to tolerate bisphosphonates
- Zonisamide – Focal epilepsy
- Zonisamide – Developmental and epileptic encephalopathies

**Proposals ranked outside meeting**

**Cost-neutral or cost-saving:**

- Acalibrutinib – CLL 2L and 3L treatment with or without 17P deletion
- Zanubrutinib - CLL 2L treatment, with 17p deletion
- Zanubrutinib – CLL 3L treatment, without 17p deletion

**Recommended for decline:**

- Ibrutinib – Waldenstroms Macroglobulinemia, relapsed within 5 years of treatment, under 55 year
- Ivermectin – Prevention and/or treatment of COVID-19

Under assessment:

- Macitentan – Pulmonary arterial hypertension

Options for investment – new:

- Sodium hypochlorite - Moderate to severe atopic dermatitis
- Methylnaltrexone - Opioid induced constipation (outside palliative care)
- Enzalutamide - Metastatic, castration resistant prostate cancer, contraindicated to abiraterone

Options for investment – reranked:

- Eplerenone - Hypertension, treatment refractory, intolerant to spironolactone
- Lenvatinib mesilate - Unresectable hepatocellular carcinoma, 1L