

## Issue 20: December 2024

### Almost a third of approvals were cancer related!

This newsletter summarises final decisions from HTA bodies around the world from published reports in December 2024.

**Good news** for: **Aflibercept**, approved for diabetic macular oedema and subfoveal choroidal neovascularisation in Australia; **Ivosidenib**, approved for bile duct cancer in Australia and France; and **Pembrolizumab**, approved for renal cell carcinoma in Australia and endometrial and cervical cancer in Austria.

**Mixed news** for: **Durvalumab**, approved for endometrial cancer in Australia and, in combination with carboplatin, paclitaxel and olaparib in Germany, but not approved for NSCLC in Scotland; **Epcoritamab**, approved for relapsed or refractory diffuse large B-cell lymphoma in Australia but not approved for follicular lymphoma in Germany; and **Olaparib**, approved for metastatic castration-resistant prostate cancer in Australia but not approved for endometrial cancer in Germany.

**Bad news** for: **Faricimab**, not approved for macular oedema in Germany; **Risankizumab**, not approved for ulcerative colitis in Germany or Crohn's disease in Australia; and **Ramucirumab**, not approved for advanced or metastatic gastric or gastroesophageal junction cancer in Brazil.

“  
**75 Approvals**  
11 with special arrangements  
3 with orphan drug status

“  
**32 Not approved**  
**6 Excluded**  
**1 Terminated**

“  
**5 Evidence reviews**

# HTANGEL

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## Pharmacological Technologies



France  
HAS AP388

Blood  
Hemophilia A and B  
CONCIZUMAB

✓ Approved



Germany  
IQWiG G24-22

Blood  
Congenital thrombotic-  
thrombocytopenic purpura  
RADAMTS13

✓ Approved  
orphan drug  
status



Germany  
IQWiG A24-94

Blood  
Paroxysmal nocturnal  
hemoglobinuria  
CROVALIMAB

✗ Not  
approved



Australia  
PBAC

Cancer  
NSCLC  
AMIVANTAMAB

✓ Approved



Wales  
AWTTC 4883

Blood  
Severe haemophilia A  
or haemophilia B  
MARSTACIMAB

✗ Excluded



Germany  
IQWiG A24-71

Cancer  
Diffuse large B-cell  
lymphoma or high-grade B-  
cell lymphoma  
AXICBTAGENE CILOLEUCEL

✓ Approved



Australia  
PBAC

Blood  
Myelofibrosis with  
moderate to severe  
anaemia  
MOMELOTINIB

✓ Approved



Australia  
PBAC

Cancer  
MRD-negative B-cell  
precursor acute  
lymphoblastic leukaemia  
BLINATUMOMAB

✓ Approved



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## Pharmacological Technologies



Australia  
PBAC

Cancer  
Locally advanced or  
metastatic breast cancer  
CAPIVASERTIB

Not  
approved



Germany  
IQWiG A24-87

Cancer  
Endometrial  
carcinoma  
DURVALUMAB

Not  
approved



Wales  
AWTTC 6321

Cancer  
Metastatic colorectal  
cancer  
CETUXIMAB

Not  
approved



Scotland  
SMC 2677

Cancer  
Resectable NSCLC  
DURVALUMAB

Not  
approved



England  
NICE TA1021

Cancer  
Advanced non-small-  
cell lung cancer  
CRIZOTINIB

Approved  
with special  
conditions



Wales  
AWTTC 4136

Cancer  
Extensive-stage  
small-cell lung cancer  
DURVALUMAB

Excluded



Austria  
AIHTA 191

Cancer  
Multiple myeloma  
DARATUMUMAB,  
BORTEZOMIB, LENALIDOMIDE,  
DEXAMETHASONE

Approved



Germany  
IQWiG A24-86

Cancer  
Endometrial carcinoma  
DURVALUMAB, CARBOPLATIN,  
PACLITAXEL, OLAPARIB

Approved  
with special  
conditions



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## Pharmacological Technologies



Australia  
PBAC

**Cancer**

Advanced, metastatic or recurrent endometrial cancer

DURVALUMAB, OLAPARIB



Australia  
PBAC

**Cancer**

Relapsed or refractory diffuse large B-cell lymphoma

EPCORITAMAB



England  
NICE TA1023

**Cancer**

Relapsed and refractory multiple myeloma

ELRANATAMAB



Germany  
IQWiG A24-95

**Cancer**

Follicular lymphoma

EPCORITAMAB



Australia  
PBAC

**Cancer**

Locally advanced or metastatic urothelial cancer

ENFORTUMAB VEDOTIN



Australia  
PBAC

**Cancer**

Metastatic pancreatic adenocarcinoma

IRINOTECAN



Australia  
PBAC

**Cancer**

Non-metastatic hormone-sensitive prostate cancer

ENZALUTAMIDE



France  
HAS AP423

**Cancer**

Biliary tract cancer

IVOSIDENIB



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## Pharmacological Technologies



Australia  
PBAC

Cancer  
Bile duct cancer  
IVOSIDENIB

✓ Approved



Australia  
PBAC

Cancer  
Urothelial carcinoma  
NIVOLUMAB

✓ Approved



Australia  
PBAC

Cancer  
Locally advanced or  
metastatic prostate  
carcinoma  
LEUPRORELIN

✓ Approved



Brazil  
CONITEC

Cancer  
Advanced or metastatic  
stomach or esophagogastric  
junction cancer  
NIVOLUMAB

✗ Not  
approved



Austria  
AIHTA 193

Cancer  
Epithelial ovarian, fallopian  
tube and primary peritoneal  
cancer  
MIRVETUXIMAB  
SORAVTANSINE

✓ Approved



France  
HAS AP379

Cancer  
Colorectal cancer  
NIVOLUMAB,  
IPILIMUMAB

✗ Not  
approved



Australia  
PBAC

Cancer  
NSCLC  
NIVOLUMAB

✗ Excluded



Germany  
IQWiG A24-88

Cancer  
Endometrial  
carcinoma  
OLAPARIB

✗ Not  
approved



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## Pharmacological Technologies



Australia  
PBAC

Cancer  
Metastatic castration-resistant prostate cancer  
OLAPARIB

✓ Approved



Austria  
AIHTA 194

Cancer  
Locally advanced cervical cancer  
PEMBROLIZUMAB, CRT

✓ Approved



Wales  
AWTTC 6340

Cancer  
Metastatic colorectal cancer  
PANITUMUMAB

✗ Not approved



Brazil  
CONITEC

Cancer  
Chronic myeloid leukemia  
PONATINIB

✓ Approved



Australia  
PBAC

Cancer  
Renal cell carcinoma  
PEMBROLIZUMAB

✓ Approved



Brazil  
CONITEC

Cancer  
Advanced or metastatic gastric or gastroesophageal junction cancer  
RAMUCIRUMAB, PACLITAXEL

✗ Not approved



Austria  
AIHTA 195

Cancer  
Endometrial carcinoma  
PEMBROLIZUMAB

✓ Approved



Australia  
PBAC

Cancer  
Breast cancer  
RIBOCICLIB

✓ Approved



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## Pharmacological Technologies



**Austria**  
AIHTA 192

**Cancer**  
Extensive-stage  
small cell lung cancer  
SERPLULIMAB



**Scotland**  
SMC 2684

**Cancer**  
Marginal zone  
lymphoma  
ZANUBRUTINIB



**Australia**  
PBAC

**Cancer**  
Oesophageal squamous  
cell carcinoma  
TISLELIZUMAB



**Australia**  
PBAC

**Cardiovascular**  
Pulmonary arterial  
hypertension  
MACITENTAN, TADALAFIL



**England**  
NICE TA1024

**Cancer**  
Advanced oesophageal  
squamous cell cancer  
TORIPALIMAB



**Australia**  
PBAC

**Cardiovascular**  
Prevention of venous  
thromboembolism, Chronic  
stable atherosclerotic disease  
RIVAROXABAN



**Brazil**  
CONITEC

**Cancer**  
Advanced or metastatic  
stomach or esophagogastric  
junction cancer  
TRASTUZUMAB



**Australia**  
PBAC

**Cardiovascular**  
Chronic heart failure  
SACUBITRIL,  
VALSARTAN



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## Pharmacological Technologies



Germany  
IQWiG A24-96

Cardiovascular  
Pulmonary arterial  
hypertension  
SOTATERCEPT

Not  
approved



Australia  
PBAC

Endocrine  
Menopausal hormone  
therapy  
ESTRADIOL,  
PROGESTERONE

Approved



Australia  
PBAC

Endocrine  
Adrenal insufficiency  
HYDROCORTISONE

Not  
approved



Australia  
PBAC

Endocrine  
Diabetes mellitus  
INSULIN ASPART

Not  
approved



Germany  
IQWiG A24-90

Endocrine  
Type 1 diabetes  
mellitus  
INSULIN CODEC

Not  
approved



Germany  
IQWiG A24-91

Endocrine  
Type 2 diabetes  
mellitus  
INSULIN ICODEC

Not  
approved



Australia  
PBAC

Endocrine  
Type 2 diabetes  
mellitus  
SEMAGLUTIDE

Approved



Australia  
PBAC

Endocrine  
Type 2 diabetes  
mellitus  
TIRZEPATIDE

Not  
approved





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## Pharmacological Technologies



Australia  
PBAC

Eye  
Diabetic macular  
oedema  
AFLIBERCEPT

✓ Approved



Australia  
PBAC

Gastrointestinal  
Ulcerative colitis  
BUDESONIDE

✓ Approved



Australia  
PBAC

Eye  
Subfoveal choroidal  
neovascularisation  
AFLIBERCEPT

✓ Approved



Australia  
PBAC

Gastrointestinal  
Chronic sialorrhea  
INCOBOTULINUMTOXINA

✗ Excluded



England  
NICE TA1022

Eye  
Wet age-related macular  
degeneration  
BEVACIZUMAB GAMMA

✓ Approved  
with special  
conditions



Germany  
IQWiG A24-84

Gastrointestinal  
Ulcerative colitis  
RISANKIZUMAB

✗ Not  
approved



Germany  
IQWiG A24-85

Eye  
Visual impairment due to  
macular oedema  
FARICIMAB

✗ Not  
approved



Australia  
PBAC

Gastrointestinal  
Crohn disease  
RISANKIZUMAB

✗ Not  
approved



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## Pharmacological Technologies



Australia  
PBAC

Genetic & Metabolic  
Hereditary  
angioedema  
GARADACIMAB

✓ Approved



Australia  
PBAC

Genetic & Metabolic  
Hereditary  
angioedema  
LANADELUMAB

✓ Approved



Australia  
PBAC

Genetic & Metabolic  
Phenylketonuria  
GLYCOMACROPEPTIDE AND  
ESSENTIAL AMINO ACIDS  
WITH VITAMINS AND  
MINERALS

✓ Approved



England  
NICE TA1026

Genetic & Metabolic  
Overweight and  
obesity  
TIRZEPATIDE

✓ Approved



Canada  
CDA HC0097

Genetic & Metabolic  
Hereditary  
angioedema  
ICABITANT

✓ Approved



Australia  
PBAC

Genetic & Metabolic  
Proven inborn errors of  
protein metabolism  
TRIGLYCERIDES, LONG CHAIN  
WITH GLUCOSE POLYMER

✓ Approved  
with special  
conditions



Australia  
PBAC

Genetic & Metabolic  
Familial heterozygous  
hypercholesterolaemia and  
Non-familial  
hypercholesterolaemia  
INCLISIRAN

✓ Approved



Australia  
PBAC

Genetic & Metabolic  
Hereditary  
transthyretin-mediated  
(hATTR) amyloidosis  
VUTRISIRAN

✓ Approved



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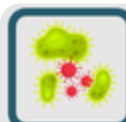
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## Pharmacological Technologies



Germany  
IQWiG A24-92

Genitourinary  
Uterine myoma  
LINZAGOLIX



Germany  
IQWiG G24-31

Infection  
Bacterial infections,  
multiple infections  
CEFEPIME,  
ENMETAZOBACTAM



Australia  
PBAC

Genitourinary  
Endometriosis  
RELUGOLIX, ESTRADIOL,  
NORETHISTERONE ACETATE



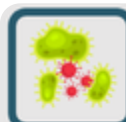
Australia  
PBAC

Infection  
Post-transplant  
cytomegalovirus  
MARIBAVIR



Scotland  
SMC 2696

Genitourinary  
Overactive bladder  
(OAB) syndrome  
VIBEGRON



Australia  
PBAC

Infection  
Prevention of  
pneumococcal disease  
PNEUMOCOCCAL  
VACCINE



Germany  
IQWiG G24-21

Infection  
Bacterial infections,  
multiple infections  
AZTREONAM, AVIBACTAM



Australia  
PBAC

Infection  
Respiratory syncytial  
virus  
RESPIRATORY SYNCYTIAL  
VIRUS VACCINE



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## Pharmacological Technologies



Australia  
PBAC

**Musculoskeletal**

Osteoporosis, giant cell tumor  
of bone, bone metastases

**DENOSUMAB**

✓ Approved



Australia  
PBAC

**Neurology**

Seizures associated with  
Dravet Syndrome

**FENFLURAMINE**

✓ Approved



Australia  
PBAC

**Musculoskeletal**

Rheumatoid arthritis

**INFLIXIMAB**

✗ Not  
approved



Australia  
PBAC

**Neurology**

Multiple sclerosis

FINGOLIMOD,  
OFATUMUMAB, SIPONIMOD

✓ Approved



Australia  
PBAC

**Musculoskeletal**

Fibrodysplasia  
Ossificans Progressiva

**PALOVAROTENE**

✓ Approved



Australia  
PBAC

**Neurology**

Advanced Parkinson's  
disease

FOSLEVODOPA,  
FOSCARBIDOPA

✓ Approved



Australia  
PBAC

**Neurology**

Chronic migraine

**ERENUMAB**

✓ Approved



Australia  
PBAC

**Neurology**

Moderate to severe spasticity  
of the upper limb Dynamic  
equinus foot deformity

**INCOBOTULINUMTOXINA**

✗ Excluded



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## Pharmacological Technologies



Scotland  
SMC 2507

**Neurology**

**Advanced Parkinson's disease**

LEVODOPA, CARBIDOPA MONOHYDRATE, ENTACAPONE

Not approved



Australia  
PBAC

**Other**

Plaque psoriasis, psoriatic arthritis, Crohn disease, fistulising, ulcerative colitis

USTEKINUMAB

Approved



Australia  
PBAC

**Neurology**

**Advanced Parkinson's disease**

LEVODOPA, CARBIDOPA MONOHYDRATE, ENTACAPONE

Approved with special conditions



Australia  
PBAC

**Pregnancy**

**Contraception**

DROSPIRENONE

Approved



Australia  
PBAC

**Neurology**

**Neuromyelitis Optica Spectrum Disorder**

RAVULIZUMAB

Approved



Australia  
PBAC

**Pregnancy**

**Stimulation of follicular development**

FOLLITROPIN ALFA, LUTROPIN ALFA

Approved



England  
NICE TA1025

**Neurology**

**Relapsing multiple sclerosis**

UBLITUXIMAB

Approved with special conditions



Australia  
PBAC

**Respiratory**

Idiopathic pulmonary fibrosis, Progressive fibrosing Interstitial lung disease

NINTEDANIB

Not approved



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## Pharmacological Technologies



Australia  
PBAC

### Respiratory

Severe asthma,  
bronchospasm and dyspnoea  
associated with COPD

**TIOTROPIUM**

✓ Approved



Australia  
PBAC

### Respiratory

COPD

**TIOTROPIUM,  
OLODATEROL**

✓ Approved



Australia  
PBAC

### Skin

Severe atopic  
dermatitis

**ABROCITINIB**

✓ Approved



Australia  
PBAC

### Skin

Dermatoses

**CLOBETASOL**

✓ Approved



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## Non-pharmacological Technologies



**Brazil**  
**CONITEC**

**Cardiovascular**  
Complex cardiac  
arrhythmias  
**CONTACT FORCE**  
**CATHETER**



**Australia**  
**PBAC**

**Neurology**  
GA-1 Pyridoxine  
dependent epilepsy  
**AMINO ACID FORMULA**



**Australia**  
**PBAC**

**Genetic & Metabolic**  
Phenylketonuria  
**AMINO ACID**  
**FORMULA**



**England**  
**NICE IPG797**

**Neurology**  
**Parkinson's**  
MRI-GUIDED FOCUSED  
ULTRASOUND  
SUBTHALAMOTOMY



**Australia**  
**PBAC**

**Genetic & Metabolic**  
Methylmalonic acidaemia  
(MMA), Propionic acidaemia  
(PA)  
**AMINO ACID FORMULA**



**England**  
**NICE IPG796**

**Neurology**  
Moderate to severe  
tremor in Parkinson's  
MRI-GUIDED FOCUSED  
ULTRASOUND THALAMOTOMY



**England**  
**NICE IPG795**

**Musculoskeletal**  
**Prostheses**  
INTRAOSSEOUS  
TRANSCUTANEOUS IMPLANT



**Australia**  
**PBAC**

**Other**  
Assorted protein  
intolerances  
**AMINO ACID FORMULA**



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## Non-pharmacological Technologies



England  
NICE HTE19

Respiratory  
COPD  
DIGITAL  
TECHNOLOGIES



Brazil  
CONITEC

Skin  
Skin burns  
AMNIOTIC MEMBRANE  
TRANSPLANTATION



Brazil  
CONITEC

Surgery  
Organ failure and other  
indications  
SMALL BOWEL TRANSPLANT,  
MULTIVISCERAL TRANSPLANT





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## Diagnostic Testing



South Korea  
NECA HTA-2024-50

**Mental Health**  
**Mental illness**  
QUANTITATIVE  
ELECTROENCEPHALOGRAPHY  
(QEEG)



England  
NICE DG62

**Respiratory**  
Obstructive sleep apnoea  
hypopnoea syndrome  
HOME-TESTING DEVICES



South Korea  
NECA HTA-2024-48

**Respiratory**  
**Respiratory**  
RESPIRATORY VOLUME  
MONITORING



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## Other Guidance



**Canada**  
CDA RC1559

### Cancer

Polyps, adenomas,  
precancerous lesions,  
colorectal cancer

AI-ASSISTED COLONOSCOPY



Evidence  
review



**Spain**  
AQuAS

### Cancer

Prostate, bladder, rectal  
and cervical cancer

RADIOTHERAPY



Evidence  
review



**Switzerland**  
FOPH

### Infection

Influenza A and B

OSELTAMIVIR,  
BALOXAVIR MARBOXIL



Evidence  
review



**Canada**  
CDA RC1556

### Mental Health

ADHD

ADHD MEDICATION



Evidence  
review



**United States**  
AHRQ

### Mental Health

OCD

DIAGNOSIS AND  
MANAGEMENT



Evidence  
review

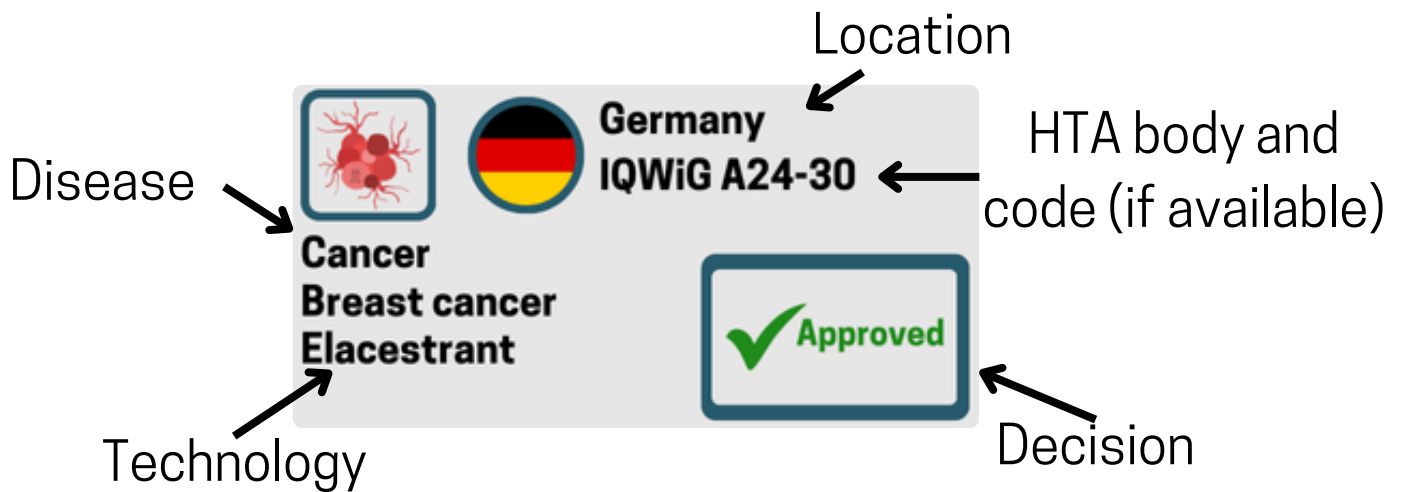


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## Further Information

HTAngel is designed to help keep you up to date with the latest HTA decisions around the world. Below is a breakdown of the tiles in the newsletter.



At Crystallise we aim to provide an innovative approach to processing information, using software tools to automate processes that are slower and less accurate when done by humans. Our approach provides clients with greater transparency and scope than they could find for the same budget elsewhere. We work with a network of experts and organisations that help us support clients efficiently and effectively, and are proud of our flexible and ingenious way of solving their problems.

For further information about HTAngel contact [newsletter@crystallise.com](mailto:newsletter@crystallise.com)

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