

## Issue 16: August 2024

### Busy month for cancer with 42 submissions, but only 52% approval rate!

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

#### Good news for:

- **Epcoritamab**, approved for diffuse large B-cell lymphoma in France and relapsed refractory follicular lymphoma in Austria.
- **Iptacopan**, approved for paroxysmal nocturnal haemoglobinuria in Australia and Germany.
- **Idecabtagene vicleucel**, approved for multiple myeloma in France.

#### Mixed news for:

- **Fezolinetant**, approved for vasomotor symptoms of menopause in patients where hormone therapy is not an option but submission withdrawn in Scotland.
- **Linzagolix**, approved for uterine fibroids in England but not in Australia.
- **Pembrolizumab**, approved for oesophageal, gastroesophageal and gastric cancer in England but not approved for NSCLC in Germany.
- **Selpercatinib**, approved for NSCLC in Australia but not approved for solid tumours and thyroid carcinoma in Germany.

#### Bad news for:

- **Nirsevimab**, not approved for RSV infections in Germany and Australia.
- **Nivolumab**, not approved for unresectable malignant mesothelioma in Australia (with ipilimumab) and submission not made for stage IIB or C melanoma in Scotland.
- **Efgartigimod alfa**, not approved for generalized autoimmune myasthenia gravis in France.

“ —  
**58 Approvals**  
13 with special  
arrangements  
4 with orphan drug  
status

“ —  
**43 Not  
approved**  
**3 Excluded  
submissions**  
**1 Terminated  
submission**

“ —  
**5 Evidence  
reviews**

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## Pharmacological Technologies



Scotland  
SMC 2649

Blood  
Haemophilia B  
Etranacogene  
dezaparvovec



Australia  
PBAC

Cancer  
Prostate cancer  
Apalutamide



Australia  
TGA

Blood  
Paroxysmal nocturnal  
haemoglobinuria  
Iptacopan



Australia  
PBAC

Cancer  
Renal cell carcinoma  
Avelumab



Germany  
IQWiG G23-26

Blood  
Paroxysmal nocturnal  
hemoglobinuria  
Iptacopan



Australia  
PBAC

Cancer  
Merkel cell  
carcinoma  
Avelumab



Australia  
PBAC

Blood  
Paroxysmal nocturnal  
hemoglobinuria  
Iptacopan



Germany  
IQWiG G24-07

Cancer  
Malignant glioma  
Dabrafenib



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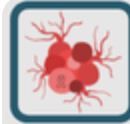
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## Pharmacological Technologies



Austria  
AIHTA 182

Cancer  
Endometrial cancer  
Durvalumab



Austria  
AIHTA 183

Cancer  
Relapsed refractory  
follicular lymphoma  
Epcoritamab



Australia  
PBAC

Cancer  
Relapsed and refractory  
multiple myeloma  
Elranatamab



Austria  
AIHTA 180

Cancer  
Urothelial carcinoma  
Erdafitinib



England  
NICE TA994

Cancer  
Prostate cancer  
Enzalutamide



Australia  
PBAC

Cancer  
Chronic lymphocytic  
leukaemia and small  
lymphocytic lymphoma  
Ibrutinib



France  
HAS AP361

Cancer  
Diffuse large B-cell  
lymphoma  
Epcoritamab



France  
HAS AP365

Cancer  
Multiple myeloma  
Idecabtagene  
vicleucel



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## Pharmacological Technologies



Australia  
PBAC

Cancer  
Bile duct cancer  
Ivosidenib

Not approved



Australia  
PBAC

Cancer  
Unresectable malignant  
mesothelioma  
Nivolumab, ipilimumab

Not approved



Australia  
PBAC

Cancer  
Tumours (various)  
Lanreotide

Approved



Austria  
AIHTA 181

Cancer  
Refractory follicular  
lymphoma or diffuse  
large B-cell lymphoma  
Odronextamab

Approved



Germany  
IQWiG A24-50

Cancer  
Myelodysplastic  
syndromes  
Luspatercept

Not approved



Australia  
PBAC

Cancer  
Breast cancer  
Olaparib

Approved



Scotland  
SMC 2704

Cancer  
Stage IIB or IIC  
melanoma  
Nivolumab

Not approved



England  
NICE TA737

Cancer  
Oesophageal and gastro-  
oesophageal junction  
cancer  
Pembrolizumab

Approved  
with special  
conditions



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## Pharmacological Technologies



England  
NICE TA997

**Cancer**

Gastric or gastro-oesophageal junction adenocarcinoma  
Pembrolizumab



Brazil  
CONITEC

**Cancer**

Breast cancer  
Pertuzumab,  
trastuzumab



Germany  
IQWiG A24-47

**Cancer**

NSCLC (adjuvant)  
Pembrolizumab



Brazil  
CONITEC

**Cancer**

Breast cancer  
Pertuzumab,  
trastuzumab



Germany  
IQWiG A24-46

**Cancer**

NSCLC (neoadjuvant + adjuvant)  
Pembrolizumab



England  
NICE TA995

**Cancer**

Prostate cancer  
Relugolix



Canada  
CDA RC1544-000

**Cancer**

Various cancers  
Pembrolizumab,  
cemiplimab, immune  
checkpoint inhibitors



Germany  
IQWiG A24-63

**Cancer**

Solid tumours  
Selpercatinib



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## Pharmacological Technologies



Germany  
IQWiG A24-62

Cancer  
Thyroid carcinoma  
Selpercatinib



France  
HAS AP184

Cancer  
Uveal melanoma  
Tebentafusp



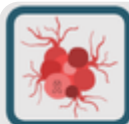
Australia  
PBAC

Cancer  
NSCLC  
Selpercatinib



France  
HAS AP371

Cancer  
Neuroblastoma  
Temozolomide



Australia  
PBAC

Cancer  
Prostate cancer  
Talazoparib



Germany  
IQWiG G24-08

Cancer  
Malignant glioma  
Trametinib



Scotland  
SMC 2705

Cancer  
Relapsed and refractory  
multiple myeloma  
Talquetamab



Scotland  
SMC 2706

Cancer  
Advanced NSCLC  
Trastuzumab  
deruxtecan



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## Pharmacological Technologies



Scotland  
SMC 2654

Cancer  
Metastatic colorectal  
cancer  
Trifluridine/tipiracil



Australia  
PBAC

Cardiovascular  
Acute coronary  
syndrome  
Prasugrel



Wales  
AWTTC 5286

Cancer  
Metastatic colorectal  
cancer  
Trifluridine/tipiracil



Australia  
PBAC

Endocrine  
Type 2 diabetes  
mellitus  
Dulaglutide



Australia  
PBAC

Cancer  
Waldenström  
macroglobulinaemia  
Zanubrutinib



Australia  
PBAC

Endocrine  
Symptoms of  
menopause  
Estradiol



France  
HAS AP372

Cardiovascular  
Eosinophilic  
granulomatosis  
Benralizumab



Scotland  
SMC 2702

Endocrine  
Vasomotor symptoms  
of menopause  
Fezolinetant



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## Pharmacological Technologies



Germany  
IQWiG A24-69

Endocrine  
Vasomotor symptoms  
of menopause  
Fezolinetant



Australia  
PBAC

Eye  
Retinal vein  
occlusion  
Faricimab



Germany  
IQWiG A24-15

Endocrine  
Vasomotor symptoms  
of menopause  
Fezolinetant



Australia  
PBAC

Gastrointestinal  
Progressive familial  
intrahepatic cholestasis  
Odevixibat



Australia  
PBAC

Endocrine  
Androgen deficiency  
Testosterone



England  
NICE TA998

Gastrointestinal  
Ulcerative colitis  
Risankizumab



Wales  
AWTTC 5178

Eye  
Macular oedema  
Faricimab



Australia  
PBAC

Gastrointestinal  
Chronic pouchitis  
Vedolizumab





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## Pharmacological Technologies



Australia  
PBAC

Genetic & Metabolic  
Von Hippel-Lindau  
(VHL) disease  
Belzutifan



England  
NICE TA996

Genitourinary  
Fibroids  
Linzagolix



England  
NICE TA993

Genetic & Metabolic  
X-linked  
hypophosphataemia  
Burosumab



Australia  
PBAC

Genitourinary  
Uterine fibroids  
Linzagolix



Australia  
PBAC

Genetic & Metabolic  
Hypercalcaemia  
Synthetic milk  
powder



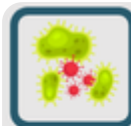
Wales  
AWTTC 2154

Genitourinary  
Overactive bladder  
Vibegron



Australia  
PBAC

Genitourinary  
Endometriosis  
Dienogest



Australia  
TGA

Infection  
Chronic hepatitis  
delta virus infection  
Bulevirtide acetate



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## Pharmacological Technologies



Germany  
IQWiG A24-75

Infection  
RSV lower respiratory  
tract disease  
Nirsevimab



Germany  
IQWiG A24-27

Infection  
RSV disease  
Nirsevimab



Australia  
PBAC

Infection  
RSV lower respiratory  
tract disease  
Nirsevimab



Australia  
PBAC

Infection  
RSV lower respiratory  
tract disease  
Respiratory syncytial  
virus vaccine



England  
NICE TA991

Musculoskeletal  
Osteoporosis  
Abaloparatide



Brazil  
CONITEC

Musculoskeletal  
Bone mineral disorder  
Aluminium hydroxide,  
alfacalcidol



France  
HAS AP366

Neurology  
Generalized autoimmune  
myasthenia gravis  
Efgartigimod alfa



Australia  
PBAC

Neurology  
Advanced Parkinson  
disease  
Levodopa, carbidopa,  
entacapone



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## Pharmacological Technologies



Australia  
PBAC

Neurology  
Generalised  
myasthenia gravis  
Ravulizumab



Australia  
PBAC

Other  
Multiple indications  
Adalimumab



Australia  
PBAC

Neurology  
Spinal muscular  
atrophy  
Risdiplam



Australia  
PBAC

Other  
Acute allergic reaction  
with anaphylaxis  
Adrenaline



Germany  
IQWiG A24-68

Neurology  
Multiple sclerosis  
Ublituximab



Australia  
PBAC

Other  
Chemotherapy and  
inflammatory conditions  
Methotrexate



Australia  
PBAC

Neurology  
Generalised  
myasthenia gravis  
Zilucoplan



Australia  
PBAC

Other  
Pain  
Morphine



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## Pharmacological Technologies



**Australia**  
PBAC

**Other**

**Crohn disease, Severe  
chronic plaque psoriasis  
Ustekinumab**



**Australia**  
PBAC

**Pregnancy**

**Oral contraceptive  
Drospirenone with  
ethinylestradiol**



**Australia**  
PBAC

**Pregnancy**

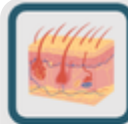
**Luteal phase support  
Progesterone**



**Australia**  
PBAC

**Pregnancy**

**Assisted reproductive  
technology  
Progesterone**



**Germany**  
IQWiG A24-45

**Skin**

**Atopic dermatitis  
Abrocitinib**



**Brazil**  
CONITEC

**Skin**

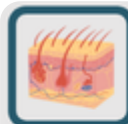
**Atopic dermatitis  
Abrocitinib, baricitinib,  
dupilumab, upadacitinib**



**Brazil**  
CONITEC

**Skin**

**Atopic dermatitis  
Abrocitinib, dupilumab,  
upadacitinib**



**Brazil**  
CONITEC

**Skin**

**Atopic dermatitis  
Dupilumab**



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## Non-pharmacological Technologies



South Korea  
NECA HTA-2024-34

Cancer  
Prostate cancer  
Irreversible  
electroporation

Approved  
with special  
conditions



Australia  
PBAC

Eye  
Severe dry eye  
syndrome  
Propylene glycol

Approved



Argentina  
IECS

Cancer  
Liver metastases  
Liver transplantation

Not  
approved



Australia  
PBAC

Genetic & Metabolic  
Cystic fibrosis  
Pancreatic extract

Not  
approved



Argentina  
IECS

Cancer  
Rectal cancer  
Transanal Access  
Device

Not  
approved



Argentina  
IECS

Genitourinary  
Refractory urinary  
incontinence  
Sacral neuromodulation

Not  
approved



England  
NICE IPG791

Cardiovascular  
Tricuspid regurgitation  
Caval valve  
implantation

Approved  
with special  
conditions



Argentina  
IECS

Musculoskeletal  
Plantar fasciitis and/or  
rotator cuff tendinopathy  
Extracorporeal shock  
waves

Not  
approved

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## Non-pharmacological Technologies



Argentina  
IECS

**Musculoskeletal**  
Lateral epicondylitis of  
the elbow  
Extracorporeal shock  
waves



Argentina  
IECS

**Surgery**  
Venous and arterial  
anastomosis in flap  
microsurgery  
Vascular coupler



Argentina  
IECS

**Musculoskeletal**  
Bone marrow edema  
Extracorporeal shock  
waves



England  
NICE IPG792

**Neurology**  
Spinal cord injury  
Phrenic nerve pacing



England  
NICE IPG790

**Respiratory**  
Congenital central  
hypoventilation  
Phrenic nerve pacing



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## Diagnostic Testing



Spain  
AETSA

Cardiovascular  
Hypertension  
Endoscopic ultrasound  
with manometer



South Korea  
NECA PV-2024-8

Neurology  
Intracranial  
Hemorrhage  
Artificial Intelligence



South Korea  
NECA HTA-2024-33

Surgery  
Colonic lesions  
Indocyanine Green



South Korea  
NECA HTA-2024-32

Surgery  
Ureteral identification  
Near-infrared  
illuminated/lighted  
ureteral catheter



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## Other Guidance



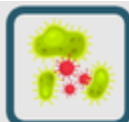
USA  
AHRQ

**Cancer**  
**Anal cancer**  
**Multiple treatment options**



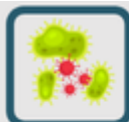
Canada  
CDA RC1543-000

**Other**  
**Various conditions and symptoms**  
**Clonidine**



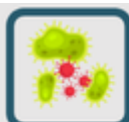
Canada  
CDA RD0070-000

**Infection**  
**Uncomplicated Gonococcal Infections**  
Ceftriaxone, cefixime,  
gentamicin, ciprofloxacin



Canada  
CDA RE0046-000

**Infection**  
**Uncomplicated Gonococcal Infections**  
N/A



Ireland  
HIQA

**Infection**  
**RSV**  
**Respiratory syncytial virus vaccine**



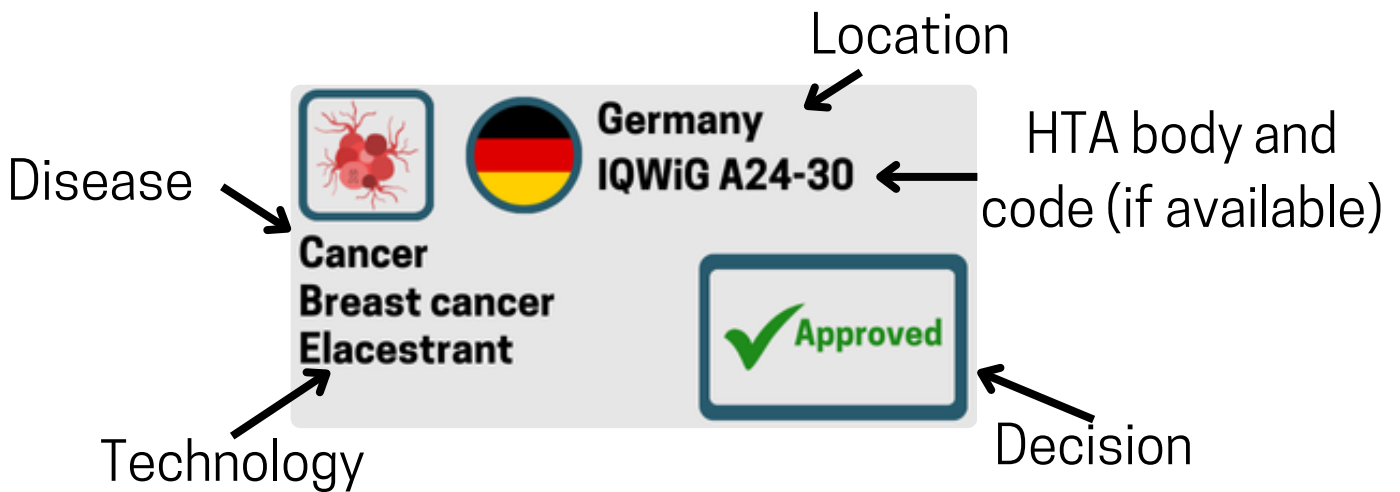


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## Further Information

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.



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

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