

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 28: August 2025

Busy summer with over 100 reported decisions!

This newsletter summarises final decisions from HTA bodies around the world from published reports in August 2025.

Good news for: **Brentuximab vedotin**, approved for Hodgkin's lymphoma in Australia and Scotland; **Durvalumab**, approved for small-cell lung cancer in Australia and hepatocellular carcinoma in England; and **Guselkumab**, approved for Crohn's disease in Australia and England and for ulcerative colitis in England.

Mixed news for: **Glofitamab**, approved for B-cell lymphoma in Australia and France but not approved in Germany; **Nirsevimab**, approved for prevention of RSV infection in Germany but not in Argentina; and **Pembrolizumab**, not approved for endometrial and urothelial cancer in Australia but approved for endometrial cancer in England.

Bad news for: **Letermovir**, not approved for prevention of cytomegalovirus infection after transplant in Germany and Scotland; **Nivolumab + ipilimumab**, not approved for hepatocellular and colorectal cancer in Australia; and **Upadacitinib**, not approved for giant cell arteritis in Germany.

“

71 Approvals

24 with special arrangements
1 with orphan drug status

“

34 Not approved

3 Excluded

9 Terminated

“

14 Evidence reviews

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Pharmacological Technologies



Australia
PBAC

Cancer
Astrocytoma,
Oligodendroglioma
VORASIDENIB

Not
approved



Australia
PBAC

Cancer
Biliary tract cancer
FUTIBATINIB

Not
approved



Australia
PBAC

Cancer
Breast cancer
RIBOCICLIB

Not
approved



England
NICE TA1086

Cancer
Breast cancer
RIBOCICLIB WITH
AROMATASE INHIBITOR

Approved



England
NICE TA1089

Cancer
Breast cancer
SACITUZUMAB
GOVITECAN

Terminated



Brazil
CONITEC

Cancer
Cancer
LAROTRECTINIB

Approved



Australia
PBAC

Cancer
Cancer
NIVOLUMAB,
IPIILIMUMAB

Terminated



Australia
PBAC

Cancer
Cancer
PEMBROLIZUMAB

Not
approved

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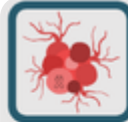
Pharmacological Technologies



Scotland
SMC2854

Cancer
Cancer
TRASTUZUMAB
DERUXTECAN

Not
approved



Scotland
SMC2821

Cancer
Gastrointestinal
stromal tumour
RIPRETINIB

Approved
with special
conditions



Australia
PBAC

Cancer
Colorectal cancer
NIVOLUMAB,
IPILIMUMAB

Not
approved



England
NICE TA1090

Cancer
Hepatocellular carcinoma
DURVALUMAB,
TREMELIMUMAB

Approved
with special
conditions



Australia
PBAC

Cancer
Endometrial cancer
PEMBROLIZUMAB

Not
approved



Australia
PBAC

Cancer
Hepatocellular carcinoma
NIVOLUMAB,
IPILIMUMAB

Not
approved



England
NICE TA1092

Cancer
Endometrial cancer
PEMBROLIZUMAB,
CARBOPLATIN, PACLITAXEL

Approved
with special
conditions



France
HAS AP490

Cancer
Leukemia
PIRTOBRUTINIB

Not
approved



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Pharmacological Technologies



France
HAS AP488

Cancer

Lung cancer

AMIVANTAMAB,
CARBOPLATIN,
PEMETREXED



Approved



England
NICE TA1091

Cancer

Lung cancer

TARLATAMAB



Not
approved



Australia
PBAC

Cancer

Lung cancer

DURVALUMAB



Approved



Australia
PBAC

Cancer

Lymphoma

ACALABRUTINIB,
BENDAMUSTINE,
RITUXIMAB



Approved



Australia
PBAC

Cancer

Lung cancer

MOBOCERTINIB



Not
approved



Australia
PBAC

Cancer

Lymphoma

BRENTUXIMAB VEDOTIN,
DOXORUBICIN, VINBLASTINE,
DACARBAZINE



Approved



Australia
PBAC

Cancer

Lung cancer

OSIMERTINIB



Approved

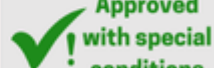


Scotland
SMC2762

Cancer

Lymphoma

BRENTUXIMAB VEDOTIN,
DOXORUBICIN, VINBLASTINE,
DACARBAZINE



Approved
with special
conditions



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Pharmacological Technologies



France
HAS AP492

Cancer
Lymphoma
EPCORITAMAB

✓ Approved



Germany
IQWiG A25-64

Cancer
Lymphoma
GLOFITAMAB,
GEMCITABINE,
OXALIPLATIN

✗ Not
approved



Australia
PBAC

Cancer
Lymphoma
GLOFITAMAB

✓ Approved



Scotland
SMC2819

Cancer
Lymphoma
ZANUBRUTINIB

✓ Approved
with special
conditions



France
HAS AP484

Cancer
Lymphoma
GLOFITAMAB

✓ Approved



Wales
AWTTC 5223

Cancer
Multiple myeloma
BELANTAMAB
MAFODOTIN

✗ Excluded



Germany
IQWiG A25-65

Cancer
Lymphoma
GLOFITAMAB

✗ Not
approved



France
HAS AP497

Cancer
Neuroblastoma
TEMOZOLOMIDE

✗ Not
approved



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Pharmacological Technologies



Australia
PBAC

Cancer
Neuroendocrine
cancer
CABOZANTINIB

✓ Approved



Australia
PBAC

Cancer
Prostate cancer
ABIRATERONE ACETATE,
PREDNISOLONE

✓ Approved



Wales
AWTTC 5350

Cancer
Urothelial cancer
PEMBROLIZUMAB

✋ Excluded



Australia
PBAC

Cardiovascular
Deep vein thrombosis,
Acute coronary syndrome
ENOXAPARIN

✓ Approved



Germany
IQWiG A25-66

Cardiovascular
Giant cell arteritis
UPADACITINIB

✗ Not
approved



Australia
PBAC

Cardiovascular
Heart failure
EPLERENONE

⚠ Terminated



South Korea
HIRA Notice 2025-129

Cardiovascular,
Genitourinary
Heart failure, Chronic
kidney disease
EMPAGLIFLOZIN

✓ Approved
with special
conditions



Australia
PBAC

Endocrine
Hypoparathyroidism
PALOPEGTERIPARATIDE

✗ Not
approved

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Pharmacological Technologies



France
HAS AP483

Endocrine
Thyrotoxicosis
TIRATRICOL

Not approved



Australia
PBAC

Endocrine
Type 1 diabetes
mellitus
INSULIN DEGLUDEC

Approved



Australia
PBAC

Endocrine
Type 2 diabetes
mellitus
TIRZEPATIDE

Terminated



Australia
PBAC

Eye
Dry Eye Disease
CARMELLOSE, GLYCEROL,
HYALURONIC ACID

Not approved



Australia
PBAC

Eye
Dry Eye Disease
HYALURONIC ACID,
POLYETHYLENE GLYCOL 400,
PROPYLENE GLYCOL,
HYDROXYPROPYL GUAR

Not approved



England
NICE TA1093

Eye
Eye disorders
IDEBENONE

Approved
with special
conditions



Australia
PBAC

Eye
Macular oedema, DMO,
Subfoveal choroidal
neovascularisation, AMD
AFLIBERCEPT

Approved



Australia
PBAC

Gastrointestinal
Crohn's disease
GUSELKUMAB

Approved

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Pharmacological Technologies



England
NICE TA1095

Gastrointestinal
Crohn's disease
GUSELKUMAB



Scotland
SMC2822

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



Australia
PBAC

Gastrointestinal
Primary biliary
cholangitis
SELADELPAR



England
NICE TA1094

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Australia
PBAC

Gastrointestinal
Ulcerative colitis
MIRIKIZUMAB



Australia
PBAC

Genetic & Metabolic
Activated PI3K Delta
Syndrome
LENIOLISIB



Australia
PBAC

Genetic & Metabolic
Alpha-mannosidosis
VELMANASE ALPHA



Australia
PBAC

Genetic & Metabolic
Cholestasis familial
progressive
ODEVIXIBAT



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Pharmacological Technologies



Australia
PBAC

Genetic & Metabolic
Cystic fibrosis
VANZACFTOR,
TEZACFTOR,
DEUTIVACFTOR

Not approved



Australia
PBAC

Genetic & Metabolic
Growth hormone deficiency
SOMAPACITAN

Approved



South Korea
HIRA Notice 2025-129

Genetic & Metabolic
Fabry disease
MIGALASTAT

Approved with special conditions



Australia
PBAC

Genetic & Metabolic
Growth hormone deficiency
SOMAPACITAN

Approved



Australia
PBAC

Genetic & Metabolic
Fabry disease
PEGUNIGALSIDASE
ALFA

Approved



Germany
IQWiG A25-41

Genetic & Metabolic
Hereditary angioedema
GARADACIMAB

Approved



Australia
PBAC

Genetic & Metabolic
Gaucher disease
ELIGLUSTAT, IMIGLUCERASE,
TALIGLUCERASE ALFA,
VELAGLUCERASE ALFA

Terminated



Germany
IQWiG A25-94

Genetic & Metabolic
Hereditary angioedema
GARADACIMAB

Approved



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Pharmacological Technologies



Wales
AWTTC 5403

Genetic & Metabolic
Hereditary
angioedema
GARADACIMAB



Excluded



Australia
PBAC

Genetic & Metabolic
Hereditary
Tyrosinaemia-Type 1
NITISINONE



Terminated



Germany
IQWiG G25-17

Genetic & Metabolic
MCT8 deficiency
TIRATRICOL



Approved
orphan drug
status



Australia
PBAC

Genetic & Metabolic
Porphyria
GIVOSIRAN



Terminated



Brazil
CONITEC

Genetic & Metabolic,
Cardiovascular
Obesity, Ischaemic heart
disease
SEMAGLUTIDE



Not
approved



Brazil
CONITEC

Genetic & Metabolic,
Endocrine
Obesity, Type 2 diabetes
mellitus
LIRAGLUTIDE



Not
approved



Germany
IQWiG A25-68

Infection
Cytomegalovirus
infection
LETERMOVIR



Not
approved



Germany
IQWiG A25-67

Infection
Cytomegalovirus
infection
LETERMOVIR



Not
approved

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Pharmacological Technologies



Scotland
SMC2853

Infection
Cytomegalovirus
infection
LETERMOVIR

Not
approved



Germany
IQWiG A25-33

Infection
Respiratory syncytial
virus
NIRSEVIMAB

Approved



Brazil
CONITEC

Infection
Diphtheria, Pertussis,
Tetanus, Hepatitis B, H.
influenzae, Poliomyelitis
DTAP, HEPATITIS B,
POLIOVIRUS, HIB VACCINE

Terminated



Australia
PBAC

Infection
Respiratory syncytial
virus
RSV VACCINE

Approved



Australia
PBAC

Infection
Hepatitis D
BULEVIRTIDE

Approved



Australia
PBAC

Infection
Respiratory syncytial
virus
RSV VACCINE

Approved



Argentina
IECS 1036

Infection
Respiratory syncytial
virus
NIRSEVIMAB

Not
approved



Brazil
CONITEC

Infection
Shingles
RECOMBINANT
ADJUVANTED HERPES
ZOSTER VACCINE

Not
approved



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Pharmacological Technologies



Australia
PBAC

Mental Health
Schizophrenia
ARIPIRAZOLE



Australia
PBAC

Mental Health
Schizophrenia
BREXPIRAZOLE



Australia
PBAC

Mental Health
Schizophrenia
PALIPERIDONE



Australia
PBAC

Musculoskeletal
Osteoporosis
ABALOPARATIDE



Australia
PBAC

Musculoskeletal
Osteoporosis
TERIPARATIDE



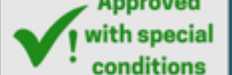
Germany
IQWiG A25-83

Musculoskeletal
Polymyalgia
rheumatica
SARILUMAB



South Korea
HIRA Notice 2025-129

Musculoskeletal, Skin
Rheumatoid arthritis,
Atopic dermatitis
BARICITINIB



Australia
PBAC

Musculoskeletal, Skin
Psoriatic arthritis, Ankylosing
spondylitis, Psoriasis, Axial
spondyloarthritis
SECUKINUMAB



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Pharmacological Technologies



**Australia
PBAC**

Musculoskeletal, Skin
Rheumatoid arthritis,
Psoriatic arthritis, Ankylosing
spondylitis, Psoriasis,
Juvenile arthritis
ETANERCEPT

✓ **Approved**



**Australia
PBAC**

**Musculoskeletal, Skin,
Gastrointestinal**
Rheumatoid arthritis, Ankylosing
spondylitis, Psoriatic arthritis, Psoriasis,
Crohn's disease, Ulcerative colitis
INFLIXIMAB

✓ **Approved**



**Australia
PBAC**

Neurology
Alzheimer's disease
DONANEMAB

✗ **Not
approved**



**Australia
PBAC**

Neurology
Lennox-Gastaut
syndrome
CANNABIDIOL

✓ **Approved
with special
conditions**



**Australia
PBAC**

Neurology
Migraine
GALCANEZUMAB

✓ **Approved**



**Australia
PBAC**

Neurology
Multiple sclerosis
OCRELIZUMAB

✓ **Approved**



South Korea
HIRA Notice 2025-129

Neurology
Neuromyelitis optica
spectrum disorder
SATRALIZUMAB

✓ **Approved
with special
conditions**



**Australia
PBAC**

Neurology
Parkinson's disease
APOMORPHINE

✓ **Approved**

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Pharmacological Technologies



Australia
PBAC

Neurology
Spasticity
INCOBOTULINUMTOXINA

✓ Approved



Australia
PBAC

Skin
Atopic dermatitis
NEMOLIZUMAB

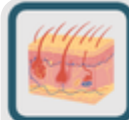
✗ Not approved



England
NICE TA1087

Other
Allergic rhinitis,
Conjunctivitis
BETULA VERRUCOSA

✓ Approved



Australia
PBAC

Skin
Atopic dermatitis
TACROLIMUS

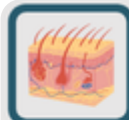
✓ Approved



Australia
PBAC

Other
Pain
METHADONE

✓ Approved



Australia
PBAC

Skin
Psoriasis
CALCIPOTRIOL,
BETAMETHASONE
DIPROPIONATE

✓ Approved



Scotland
SMC2801

Respiratory
Chronic obstructive
pulmonary disease
DUPILUMAB

✗ Not approved



Australia
PBAC

Skin, Musculoskeletal
Psoriasis, Juvenile
arthritis
ADALIMUMAB

✓ Approved with special conditions

Non-pharmacological Technologies



South Korea
NECA HTA-2025-21

Cancer

Liver cancer

**PREOPERATIVE 3D
RECONSTRUCTION FOR
LIVER RESECTION**



South Korea
HIRA Notice 2025-130

Other

Hearing loss

**BONE CONDUCTION
HEARING IMPLANT (BAHA)
SURGERY**



South Korea
HIRA Notice 2025-133

Gastrointestinal

Pancreatic disease

**ENDOSCOPIC PANCREATIC
NECROSIS REMOVAL**



Argentina
IECS 1039

Other

Pain

CRYOANALGESIA



England
NICE IPG793

Musculoskeletal

Knee cartilage defect

**SCAFFOLD INSERTION
(SINGLE-STEP, NO CELL
CULTURE)**



South Korea
NECA Innovation-2025-6

Neurology

Cognitive impairment

**METAMEMORY TRAINING
DIGITAL THERAPEUTICS**



Diagnostic Testing



South Korea
HIRA Notice 2025-133

Blood

Haemorrhage, Anaemia
CROSSMATCH IMMUNOLOGIC
TEST (NU155)



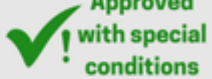
Approved



South Korea
NECA Innovation-2025-7

Cancer

Breast cancer
AI-BASED BREAST
ULTRASOUND SOFTWARE



Approved
with special
conditions



South Korea
NECA HTA-2025-22

Cancer

Gastric cancer
GASTRIC CANCER
PROGNOSIS PREDICTION
GENETIC TEST (RT-PCR)



Not
approved



South Korea
HIRA Notice 2025-133

Genetic & Metabolic

Congenital metabolic
abnormality
NEWBORN METABOLIC
SCREENING TESTS



Approved
with special
conditions



Canada
INESSS REF1188

Genetic & Metabolic

Rickets (vitamin D-
dependent)
NEONATAL SCREENING TEST
FOR VITAMIN D-DEPENDENT
RICKETS (VDDR1A)



Not
approved



Canada
INESSS REF1179

Neurology

Epilepsy
PENTOBARBITAL
HPLC-MS/MS ASSAY



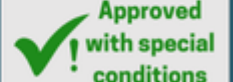
Approved



South Korea
HIRA Notice 2025-130

Other

Surgery
CONTINUOUS
TEMPERATURE
MONITORING PROBES



Approved
with special
conditions

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Other Guidance



Canada
INESSS REF1037

Cancer
Cancer (solid tumors)
TUMOR BIOMARKER
PANELS / NGS
SEQUENCING



Evidence
review



Canada
INESSS REF1175

Cancer
Lung cancer
LOW-DOSE CT LUNG
SCREENING



Evidence
review



Canada
INESSS REF1190

Cancer
Prostate cancer
EXTERNAL RADIOTHERAPY
(ULTRA-
HYPOFRACTIONATION)



Evidence
review



England
NICE HTE31

Cardiovascular
Aortic stenosis
TRANSCATHETER HEART
VALVES (VARIOUS)



Evidence
review



Scotland
SHTG

Cardiovascular
Hypertension
HOME BLOOD PRESSURE
MONITOR (UPPER ARM
VALIDATED CUFF)



Evidence
review



Canada
INESSS REF565

Cardiovascular, Respiratory
Heart failure, Respiratory
failure
EXTRACORPOREAL
MEMBRANE OXYGENATION
(ECMO)



Evidence
review



Canada
INESSS REF442

Gastrointestinal
Gastrointestinal acid
suppression, Peptic ulcer
PROTON PUMP INHIBITORS
(PPIS)



Evidence
review



Canada
INESSS REF1181

Genetic & Metabolic
Sex-linked genetic conditions
NON-INVASIVE FETAL SEX
DETERMINATION (CFDNA)



Evidence
review

Other Guidance



Sweden

SBU Evidence Map 2025

Other
Behaviour change
BEHAVIOUR CHANGE
INTERVENTIONS (VARIOUS)



Evidence
review



Ireland

HIQA protocol

Other
Substance abuse
RISK MODELLING
PROTOCOL



Evidence
review



England

NICE HTE33

Other
Surgery
BED FRAMES
(VARIOUS)



Evidence
review



Canada

INESSS REF1186

Respiratory
Chronic obstructive
pulmonary disease
MOBILE APPLICATIONS FOR
PULMONARY REHABILITATION



Evidence
review



Canada

INESSS REF1185

Respiratory
Chronic obstructive
pulmonary disease
PEPO DEVICES (EXPIRATORY
PRESSURE OSCILLATION
DEVICES)



Evidence
review



England

NICE HTE32

Skin
Venous leg ulcers
COMPRESSION PRODUCTS
(HOSIERY, BANDAGING,
WRAPS)



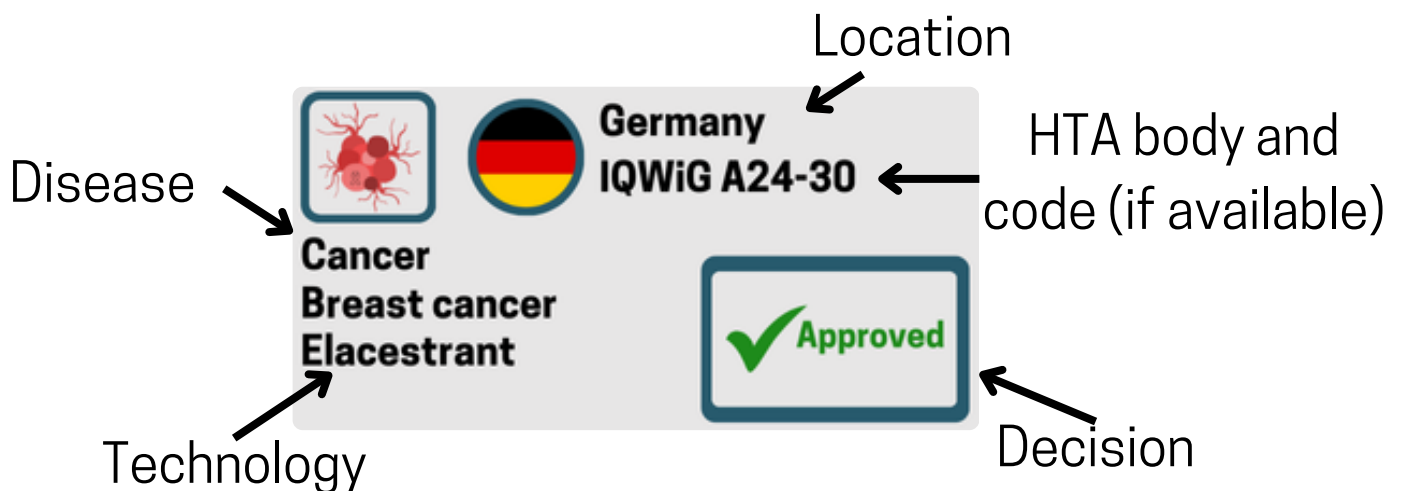
Evidence
review

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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.

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