

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 31: November 2025

Oncology remained the most active field globally, marked by significant approvals and notable rejections, reflecting ongoing scrutiny of cancer therapy evidence.

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

Good news for: Datopotamab deruxtecan, approved for HER2-negative breast cancer in Austria and approved with special conditions in Germany; **Pembrolizumab**, approved for head and neck cancer in Australia and mesothelioma in Austria; and **Tislelizumab**, approved for oesophageal, gastric, small-cell and non-small cell lung cancer and nasopharyngeal cancer in Austria.

Mixed news for: Durvalumab, approved for muscle-invasive bladder cancer in Germany and Australia, hepatocellular carcinoma in Scotland and small-cell lung cancer in Germany, but not approved for non-small-cell lung cancer in Germany; **Efgartigimod alfa**, approved for myasthenia gravis in Australia but not approved for chronic inflammatory demyelinating polyneuropathy in Germany; and **Guselkumab**, approved for Crohn's disease in Germany and Scotland and for ulcerative colitis in Scotland but not in Germany.

Bad news for: Cemiplimab, not approved for non-small-cell lung cancer in England; **Lecanemab**, not approved for early dementia in France; and **Trastuzumab deruxtecan**, not approved for gastric cancer in Australia and terminated application for HER2-low breast cancer in England.

75 Approvals

8 with special arrangements
3 with orphan drug status

34 Not approved
9 Excluded
2 Terminated

Pharmacological Technologies



Australia
PBAC

Blood
Myelofibrosis
FEDRATINIB



Australia
PBAC

Cancer
Multiple myeloma
BELANTAMAB
MAFODOTIN



England
NICE TA1110

Cancer
Prostate cancer
ABIRATERONE



Austria
AIHTA 208

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Australia
PBAC

Cancer
Chronic lymphocytic
leukaemia, Small
lymphocytic lymphoma
ACALABRUTINIB



Austria
AIHTA 196

Cancer
Malignant ascites
CATUMAXOMAB



Germany
IQWiG A25-129

Cancer
Chronic myeloid
leukaemia
ASCIMINIB



England
NICE TA1108

Cancer
Lung cancer
CEMIPLIMAB



Pharmacological Technologies



Germany
IQWiG A25-108

Cancer
Multiple myeloma
DARATUMUMAB



Austria
AIHTA 210

Cancer
Breast cancer
DATOPOTAMAB
DERUXTECAN



Germany
IQWiG A25-109

Cancer
Multiple myeloma
DARATUMUMAB



Germany
IQWiG A25-69

Cancer
Breast cancer
DATOPOTAMAB
DERUXTECAN



England
NICE TA1109

Cancer
Prostate cancer
DAROLUTAMIDE



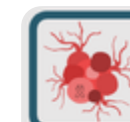
Germany
IQWiG A25-130

Cancer
Breast cancer
DATOPOTAMAB
DERUXTECAN



Germany
IQWiG A25-106

Cancer
Prostate cancer
DAROLUTAMIDE



France
HAS AP519

Cancer
Endometrial cancer
DOSTARLIMAB



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Issue 31: November 2025

Pharmacological Technologies



Wales
AWTTC 5427

Cancer
Endometrial cancer
DOSTARLIMAB



Excluded



Germany
IQWiG A25-97

Cancer
Urothelial cancer
DURVALUMAB



Approved



Australia
PBAC

Cancer
Bladder cancer
DURVALUMAB



Approved



Scotland
SMC2857

Cancer
Liver cancer
DURVALUMAB



Approved

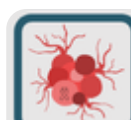


Germany
IQWiG A25-98

Cancer
Lung cancer
DURVALUMAB



Not approved



Scotland
SMC2807

Cancer
Breast cancer
ELACESTRANT



Not approved

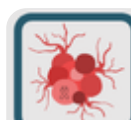


Germany
IQWiG A25-96

Cancer
Lung cancer
DURVALUMAB



Approved



Japan
C2H2403

Cancer
Multiple myeloma
ELRANATAMAB



Approved



Pharmacological Technologies



Australia
PBAC

Cancer
Lung cancer
ENCORAFENIB AND
BINIMETINIB



Scotland
SMC2804

Cancer
Multiple myeloma
ISATUXIMAB



Australia
PBAC

Cancer
Bile duct cancer
FUTIBATINIB



Austria
AIHTA 212

Cancer
Follicular lymphoma
LISOCABTAGENE
MARALEUCEL



Germany
IQWiG A25-104

Cancer
Breast cancer
INAVOLISIB



Australia
PBAC

Cancer
Lung cancer
LURBINECTEDIN



Germany
IQWiG A25-105

Cancer
Multiple myeloma
ISATUXIMAB



Australia
PBAC

Cancer
Ovarian cancer, Fallopian tube
cancer, Peritoneal cancer
MIRVETUXIMAB
SORAVTANSINE



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Issue 31: November 2025

Pharmacological Technologies



Wales
AWTTC 4896

Cancer
Leukaemia
OBECABTAGENE
AUTOLEUCEL



Excluded



Germany
IQWiG A25-101

Cancer
Follicular lymphoma
ODRONEXTAMAB



Not
approved



Germany
IQWiG A25-100

Cancer
B-cell lymphoma
ODRONEXTAMAB



Not
approved



Ireland
NCPE HTA ID 23029

Cancer
Prostate cancer
OLAPARIB



Not
approved



Australia
PBAC

Cancer
Lung cancer
OSIMERTINIB



Excluded



Australia
PBAC

Cancer
Head and neck
cancer
PEMBROLIZUMAB



Approved



Austria
AIHTA 202

Cancer
Mesothelioma
PEMBROLIZUMAB



Approved



Germany
IQWiG G25-26

Cancer
Mantle cell
lymphoma
PIRTOBRUTINIB



Approved
orphan drug
status



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Issue 31: November 2025

Pharmacological Technologies



**Australia
PBAC**

**Cancer
Merkel cell
carcinoma
RETIFANLIMAB**



Excluded



**Scotland
SMC2816**

**Cancer
Lung cancer
TARLATAMAB**



**Not
approved**



**Australia
PBAC**

**Cancer
Anal cancer
RETIFANLIMAB**



Excluded



**Austria
AIHTA 198**

**Cancer
Oesophageal cancer
TISLELIZUMAB**



Approved



**Scotland
SMC2803**

**Cancer
Breast cancer
RIBOCICLIB**



Approved



**Austria
AIHTA 199**

**Cancer
Gastric cancer,
Gastroesophageal junction
cancer
TISLELIZUMAB**



Approved



**Australia
PBAC**

**Cancer
Follicular lymphoma
TAFASITAMAB**



Excluded



**Austria
AIHTA 225**

**Cancer
Lung cancer
TISLELIZUMAB**



Approved



Pharmacological Technologies



Austria
AIHTA 233

Cancer
Nasopharyngeal cancer
TISLELIZUMAB



Australia
PBAC

Cancer
Breast cancer
TUCATINIB



Austria
AIHTA 241

Cancer
Lung cancer
TISLELIZUMAB



Australia
PBAC

Cancer
Lymphoma, Leukaemia
ZANUBRUTINIB



Australia
PBAC

Cancer
Gastric cancer, Gastroesophageal junction cancer
TRASTUZUMAB DERUXTECAN



France
HAS AP525

Cancer
Gastric cancer, Gastroesophageal junction cancer
ZOLBETUXIMAB



England
NICE TA1112

Cancer
Breast cancer
TRASTUZUMAB DERUXTECAN



Germany
IQWiG A25-66

Cardiovascular
Giant cell arteritis
UPADACITINIB



Pharmacological Technologies



Germany
IQWiG A25-125

Cardiovascular
Giant cell arteritis
UPADACITINIB



Australia
PBAC

Endocrine
Vasomotor symptoms, Menopause
ESTRADIOL WITH PROGESTERONE



Wales
AWTTC 6760

Cardiovascular
Cardiomyopathy, Amyloidosis
VUTRISIRAN



Australia
PBAC

Endocrine
Vasomotor symptoms, Menopause
FEZOLINETANT



Australia
PBAC

Cardiovascular, Genetic & Metabolic
Cardiovascular disease, Obesity
SEMAGLUTIDE



Australia
PBAC

Endocrine
Hypoactive sexual desire dysfunction
TESTOSTERONE



Australia
PBAC

Endocrine
Diabetes insipidus, Nocturnal enuresis
DESMOPRESSIN



Australia
PBAC

Eye
Subfoveal choroidal neovascularisation, Pathologic myopia
AFLIBERCEPT



Pharmacological Technologies



Australia
PBAC

Eye

Geographic atrophy, Age-related macular degeneration

PEGCETACOPLAN



Approved



Scotland
SMC2855

Gastrointestinal
Ulcerative colitis
BUDESONIDE
SUPPOSITORY

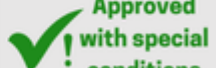


Approved



Germany
IQWiG A25-131

Gastrointestinal
Crohn's disease
GUSELKUMAB

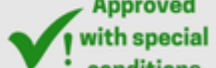


Approved
with special
conditions



Germany
IQWiG A25-75

Gastrointestinal
Crohn's disease
GUSELKUMAB



Approved
with special
conditions



Germany
IQWiG A25-132

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Not
approved



Germany
IQWiG A25-74

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Not
approved



Scotland
SMC2850

Gastrointestinal
Crohn's disease
GUSELKUMAB



Approved



Scotland
SMC2848

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Approved

Pharmacological Technologies



**Australia
PBAC**

Gastrointestinal
Crohn's disease,
Ulcerative colitis
VEDOLIZUMAB



**Australia
PBAC**

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



Ireland
NCPE HTA ID 23005

Genetic & Metabolic
**X-linked
hypophosphataemia**
BUROSUMAB



France
HAS AP500

Genetic & Metabolic
**Hutchinson-Gilford
syndrome**
LONAFARNIB



Germany
IQWiG G25-24

Genetic & Metabolic
Cystic fibrosis
DEUTIVACFTOR/
TEZACFTOR/
VANZACFTOR



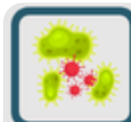
**Australia
PBAC**

Genetic & Metabolic
Tyrosinaemia
NITISINONE



**Australia
PBAC**

Genetic & Metabolic
Porphyria
GIVOSIRAN



**Australia
PBAC**

Infection
Pneumococcal infection
21-VALENT
PNEUMOCOCCAL
CONJUGATE VACCINE



Pharmacological Technologies



England
NICE TA1106

Infection

Human immunodeficiency virus
CABOTEGRAVIR



Germany
IQWiG A25-126

Infection

Cytomegalovirus
LETERMOVIR



Australia
PBAC

Infection

Herpes Zoster Virus,
Chickenpox
RECOMBINANT ZOSTER VACCINE



Australia
PBAC

Infection

Respiratory syncytial virus
RESPIRATORY SYNCYTIAL VIRUS VACCINE



Australia
PBAC

Mental Health

Bipolar disorder
LAMOTRIGINE



Australia
PBAC

Musculoskeletal,

Cancer
Osteoporosis, Bone
cancer
DENOSUMAB



Australia
PBAC

**Musculoskeletal,
Cardiovascular**

Juvenile arthritis, Rheumatoid
arthritis, Giant cell arteritis

TOCILIZUMAB



Australia
PBAC

Neurology

Myasthenia gravis
EFGARTIGIMOD ALFA



Pharmacological Technologies



Scotland
SMC2882

Neurology
ADHD
MELATONIN

Not approved



Australia
PBAC

Neurology
Friedreich's ataxia
OMAVELOXOLONE

Approved



Australia
PBAC

Neurology
Spinal muscular atrophy
ONASEMNOGENE
ABEPARVOVEC

Approved



Australia
PBAC

Neurology
Spinal muscular atrophy
RISDIPLAM

Approved



Australia
PBAC

Neurology
Amyotrophic Lateral Sclerosis
TOFERSEN

Not approved



Ireland
NCPE HTA ID 23027

Other
Systemic lupus erythematosus
ANIFROLUMAB

Approved



Ireland
NCPE HTA ID 25036

Other
Multiple indications
NIVOLUMAB

Approved



Australia
PBAC

Pregnancy
Reproduction
CETRORELIX

Approved

Pharmacological Technologies



Germany
IQWiG G25-25

Skin
Epidermolysis bullosa
BEREMAGEN
GEPPERAVEC



England
NICE TA1107

Skin
Eczema
DELGOCITINIB



Australia
PBAC

Skin
Plaque psoriasis
BIMEKIZUMAB



Australia
PBAC

Skin
Hyperhidrosis
GLYCOPYRRONIUM



Australia
PBAC

Skin
Psoriasis vulgaris
CALCIPOTRIOL WITH
BETAMETHASONE



Australia
PBAC

Skin
Eczema
DELGOCITINIB



Non-pharmacological Technologies



South Korea
NECA Innovation-
2025-10

Mental Health
Addiction
DIGITAL THERAPEUTIC
DEVICES



South Korea
NECA HTA-2025-32

Endocrine, Skin
Diabetic foot ulcer
EXTRACORPOREAL
SHOCK WAVE THERAPY



South Korea
NECA HTA-2025-30

Musculoskeletal
Arthritis
INTRA-ARTICULAR
OXYGEN-OZONE INJECTION



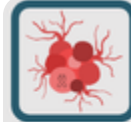
South Korea
NECA HTA-2025-28

Surgery
Transplant
PATIENT-SPECIFIC
3D-PRINTED MODEL



Australia
PBAC

Eye
Dry Eye Disease
POLYETHYLENE GLYCOL
400 WITH PROPYLENE
GLYCOL



England
NICE IPG809/
HTG763

Cancer
Rectal cancer
X-RAY
BRACHYTHERAPY



Diagnostic Testing



South Korea
NECA Innovation-
2025-9

Eye
Eye disorders
AI-ASSISTED
TECHNOLOGY



South Korea
NECA Innovation-
2025-11

Cancer
Colorectal cancer
AI-BASED IMAGING



South Korea
NECA Innovation-
2025-8

Cardiovascular
Cerebral microbleeds
AI-BASED MRI



South Korea
NECA HTA-2025-29

Cancer
Lung cancer
CT-GUIDED PERCUTANEOUS
INDOCYANINE GREEN
INJECTION WITH NEAR-
INFRARED FLUORESCENCE
IMAGING

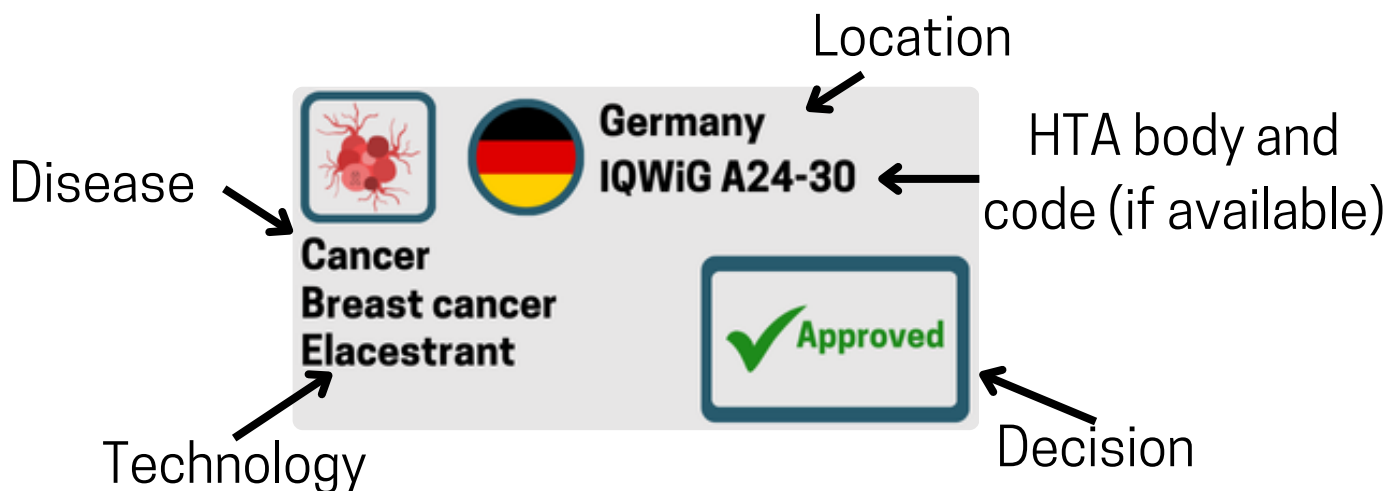


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Issue 31: November 2025

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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