

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 29: September 2025

Over 50% of technologies approved, 30% of which are cancer related!

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

Good news for: **Benralizumab**, approved with special conditions for relapsing or refractory eosinophilic granulomatosis with polyangiitis in England and exempt from submitting to Wales; **Rituximab** and **Mycophenolate**, both approved for nephrotic syndrome in Brazil; and **Tirzepatide**, approved for type 2 diabetes and obesity in England.

Mixed news for: **Belzutifan**, approved with special conditions for renal cell carcinoma in Germany but not approved in Scotland; **Guselkumab**, approved with special conditions for Crohn's disease in Germany and approved for psoriasis in South Korea, but not approved for ulcerative colitis in Germany; and **Nivolumab**, not approved for hepatocellular, non-small cell lung or colorectal cancer in Germany but approved with **ipilimumab** for advanced and metastatic cancers in Australia.

Bad news for: **Asciminib**, not approved for chronic myeloid leukaemia in Germany and Brazil; **Lecanemab**, not approved for early Alzheimer's dementia in France; and **Mirikizumab**, not approved for Crohn's disease in Germany.

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44 Approvals

12 with special arrangements
1 with orphan drug status

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27 Not approved

5 Excluded submissions

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1 Evidence review

HTANGEL

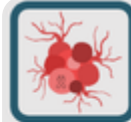
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Pharmacological Technologies



Scotland
SMC2808

Cancer
Acute lymphoblastic
leukaemia
BLINATUMOMAB



Germany
IQWiG A25-80

Cancer
Colorectal cancer
NIVOLUMAB



Germany
IQWiG A25-69

Cancer
Breast cancer
DATOPOTAMAB
DERUXTECAN



Australia
PBAC

Cancer
Gastric cancer,
Gastroesophageal junction
cancer
ZOLBETUXIMAB



Australia
PBAC

Cancer
Cancer
NIVOLUMAB &
IPIILIMUMAB



Brazil
CONITEC

Cancer
Gastrointestinal
stromal cancer
REGORAFENIB



Germany
IQWiG A25-70

Cancer
Chronic myeloid
leukaemia
ASCIMINIB



Brazil
CONITEC

Cancer
Gastrointestinal
stromal cancer
SUNITINIB



Pharmacological Technologies



Germany
IQWiG A25-79

Cancer
Hepatocellular
carcinoma
NIVOLUMAB



Scotland
SMC2865

Cancer
Lung cancer
ENCORAFENIB



Brazil
CONITEC

Cancer
Leukaemia
ARSENIC TRIOXIDE



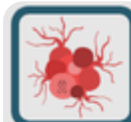
Germany
IQWiG A25-81

Cancer
Lung cancer
NIVOLUMAB



Brazil
CONITEC

Cancer
Leukaemia
ASCIMINIB



Australia
PBAC

Cancer
Lung cancer
OSIMERTINIB



Wales
AWTTC 5056

Cancer
Lung cancer
DURVALUMAB



France
HAS AP504

Cancer
Lymphoma
GLOFITAMAB



Pharmacological Technologies



Australia
PBAC

Cancer
Lymphoma
MOGAMULIZUMAB



England
NICE TA1098

Cancer
Multiple myeloma
ISATUXIMAB



Scotland
SMC2799

Cancer
Ovarian cancer, Fallopian tube cancer, Peritoneal cancer
RUCAPARIB



Germany
IQWiG A25-107

Cancer
Renal cancer
BELZUTIFAN



Germany
IQWiG A25-45

Cancer
Renal cancer
BELZUTIFAN



Scotland
SMC2864

Cancer
Renal cancer
BELZUTIFAN



England
NICE TA1097

Cancer
Urothelial cancer
ENFORTUMAB VEDOTIN



England
NICE TA1096

Cardiovascular
Eosinophilic granulomatosis, Polyangiitis
BENRALIZUMAB



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Pharmacological Technologies



Wales
AWTTC 5267

Cardiovascular
Eosinophilic granulomatosis,
Polyangiitis

BENRALIZUMAB



Excluded



Brazil
CONITEC

Endocrine, Renal
Chronic kidney disease,
Type 2 diabetes
FINERENONE



**Not
approved**



Wales
AWTTC OW31

Cardiovascular
Myocarditis
INFLIXIMAB



**Approved
with special
conditions**



Germany
IQWiG A25-75

Gastrointestinal
Crohn's disease
GUSELKUMAB



**Approved
with special
conditions**



France
HAS AP491

Cardiovascular
**Pulmonary arterial
hypertension**
SOTATERCEPT



Approved



Germany
IQWiG A25-99

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



**Not
approved**



England
NICE TA924

Endocrine
**Type 2 diabetes
mellitus**
TIRZEPATIDE



**Approved
with special
conditions**



Germany
IQWiG A25-42

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



**Not
approved**

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Pharmacological Technologies



Brazil
CONITEC

Gastrointestinal
Liver transplant
SIROLIMUS



Approved



Brazil
CONITEC

Gastrointestinal
Liver transplant
TACROLIMUS



Not
approved



Germany
IQWiG A25-74

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Not
approved



Korea
HIRA 2025-143

Gastrointestinal
Ulcerative colitis,
Crohn's disease
VEDOLIZUMAB



Approved



France
HAS AP496

Genetic & Metabolic
Cystic fibrosis
IVACAFTOR/ TEZACAFTOR /
ELEXACAFTOR



Approved



Australia
PBAC

Genetic & Metabolic
Cystic fibrosis
VANZACAFTOR,
TEZACAFTOR AND
DEUTIVACAFTOR



Approved



England
NICE TA1026

Genetic & Metabolic
Overweight, Obesity
TIRZEPATIDE



Approved
with special
conditions



France
HAS AP494

Genetic & Metabolic
Pompe disease
AVALGLUCOSIDASE
ALFA



Approved



Pharmacological Technologies



Germany
IQWiG G25-19

Infection
Bacterial infection
DALBAVACIN



Korea
HIRA 2025-143

Mental Health
ADHD
ATOMOXETINE



Brazil
CONITEC

Infection
Pneumococcal infection
PNEUMOCOCCAL
CONJUGATE VACCINE



Korea
HIRA 2025-143

Mental Health
ADHD
CLONIDINE
HYDROCHLORIDE



Brazil
CONITEC

Infection
Pneumococcal infection
PNEUMOCOCCAL
CONJUGATE VACCINES



Korea
HIRA 2025-143

Mental Health
ADHD
METHYLPHENIDATE
HCL



France
HAS AP493

Infection
Tuberculosis
PRETOMANID



Korea
HIRA 2025-143

Musculoskeletal
Rheumatoid arthritis,
Arthritis
ABATACEPT



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Pharmacological Technologies



Korea
HIRA 2025-143

Musculoskeletal
Rheumatoid arthritis,
Arthritis
TOCILIZUMAB



Brazil
CONITEC

Neurology
Plexiform
neurofibroma
SELUMETINIB



France
HAS AP460

Neurology
Alzheimer's disease,
Cognitive impairment
LECANEMAB



France
HAS AP482

Neurology
Plexiform
neurofibroma
SELUMETINIB



Wales
AWTTC 2749

Neurology
Parkinson's disease
APOMORPHINE



Brazil
CONITEC

Neurology
Spinal muscular
atrophy
NUSINERSEN



Brazil
CONITEC

Neurology
Parkinson's disease
SELEGILINE



Korea
HIRA 2025-143

Neurology, Mental
Health
Narcolepsy, ADHD
METHYLPHENIDATE
HCL



Pharmacological Technologies



Germany
IQWiG A25-72

Other
Migraine
RIMEGEPANT



Brazil
CONITEC

Renal
Nephrotic syndrome
MYCOPHENOLATE MOFETIL
/MYCOPHENOLATE SODIUM



Germany
IQWiG A25-73

Other
Migraine
RIMEGEPANT



Brazil
CONITEC

Renal
Nephrotic syndrome
RITUXIMAB



Brazil
CONITEC

Pregnancy
Postpartum
haemorrhage
CARBETOCIN



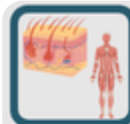
Korea
HIRA 2025-143

Skin
Psoriasis
GUSELKUMAB



Australia
PBAC

Renal
Chronic kidney
disease
DAPAGLIFLOZIN



Korea
HIRA 2025-143

Skin,
Musculoskeletal
Psoriasis, Psoriatic
arthritis
RISANKIZUMAB



Pharmacological Technologies



Korea

HIRA 2025-143

Skin,
Musculoskeletal
Psoriasis, Psoriatic
arthritis
USTEKINUMAB



Approved

Non-pharmacological Technologies



Korea
NECA RR-2025-3

Cardiovascular
Myocardial infarction
MECHANICAL
CIRCULATORY SUPPORT

 **Approved**



Argentina
IECS

Renal
Kidney function
SERUM CYSTATIN C

 **Not approved**



Argentina
IECS

Musculoskeletal
Muscle disorders
MULTICHANNEL
FUNCTIONAL ELECTRICAL
SIMULATION

 **Not approved**



Argentina
IECS

Renal
Kidney stones
ENDOSCOPIC
INTRARENAL SURGERY

 **Not approved**



Korea
NECA HTA-2025-24

Musculoskeletal
Tendinitis, Tendinopathy
PERCUTANEOUS
ULTRASONIC TENOTOMY

 **Not approved**



England
NICE HTE18

Respiratory
Chronic obstructive
pulmonary disease
PULMONARY REHABILITATION
PROGRAMMES

 **Approved with special conditions**



Brazil
CONITEC

Other
Pain
SPINAL CORD
STIMULATION

 **Approved**



England
NICE HTE19

Respiratory
Chronic obstructive
pulmonary disease
PULMONARY REHABILITATION
PROGRAMMES

 **Approved with special conditions**

Diagnostic Testing



**Brazil
CONITEC**

**Infection
Histoplasmosis
IMMUNOENZYMATIC
TEST**

 **Approved**



**Korea
NECA HTA-2025-23**

**Infection
Human
metapneumovirus
HUMAN METAPNEUMOVIRUS
ANTIGEN TEST**

 **Not
approved**



**Korea
NECA HTA-2025-25**

**Other
Coma
NONINVASIVE EEG
MONITORING**

 **Not
approved**

Other Guidance



Japan
C2H2401

Blood
Myelodysplastic
syndrome, Anaemia
LUSPATERCEPT



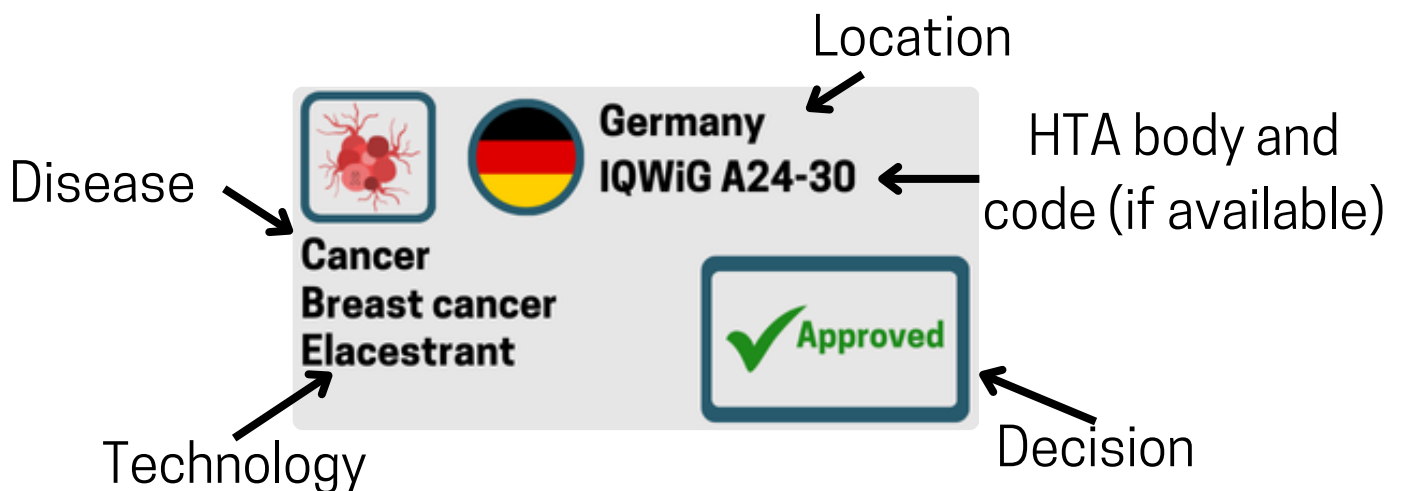
Evidence
review

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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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