

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 26: June 2025

Over 60% approvals last month!

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

Good news for: Bimekizumab, approved for moderate to severe hidradenitis suppurativa in Australia and chronic severe plaque psoriasis in South Korea; Guselkumab, approved for severe chronic plaque psoriasis in Australia and for psoriasis, palmoplantar pustulosis, and psoriatic arthritis in South Korea; and Garadacimab, approved for prophylaxis of hereditary angioedema in Germany

Mixed news for: Durvalumab, approved with tremelimumab for hepatocellular carcinoma in Australia but not in Scotland and not approved for bladder cancer in France; Fosdenopterin, approved for molybdenum cofactor deficiency type A in Germany, not approved in Wales and terminated in England; and Tislelizumab, approved for NSCLC in Germany but not in Wales and terminated in England, and not approved for oesophageal cancer in Germany.

Bad news for: Abemaciclib, not approved for breast cancer in Brazil; Ribociclib, not approved for HER2-negative early breast cancer in Germany and Wales; and Zuranolone, not approved for severe postpartum depression in France.

“ “
57 Approvals

9 with special arrangements
5 with orphan drug status

“ “
31 Not approved
2 Terminated

“ “
5 Evidence reviews

Pharmacological Technologies



Brazil
CONITEC

Blood
Haemophilia A
EMICIZUMAB

Not approved



Australia
PBAC

Blood
Paroxysmal nocturnal
haemoglobinuria
PEGCETACOPLAN

Approved



Australia
PBAC

Blood
Myelofibrosis
FEDRATINIB

Not approved



Brazil
CONITEC

Cancer
Breast cancer
ABEMACICLIB

Not approved



Germany
IQWiG G25-11

Blood
Myelofibrosis
FEDRATINIB

Approved
orphan drug
status



Australia
PBAC

Cancer
Lung cancer
ALECTINIB

Approved



England
NICE TA1073

Blood
Haemophilia B
MARSTACIMAB

Approved
with special
conditions



France
HAS AP478

Cancer
Lung cancer
AMIVANTAMAB &
LAZERTINIB

Not approved

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Pharmacological Technologies



Brazil
CONITEC

Cancer
Leukaemia
ARSENIC TRIOXIDE

Not approved



France
HAS AP467

Cancer
Bladder cancer
DURVALUMAB

Not approved



England
NICE TA1071

Cancer
Lung cancer
ATEZOLIZUMAB

Approved with special conditions



Scotland
SMC2735

Cancer
Liver cancer
DURVALUMAB

Not approved



Germany
IQWiG G25-09

Cancer
Acute lymphoblastic leukaemia
BLINATUMOMAB

Approved orphan drug status



Australia
PBAC

Cancer
Hepatocellular carcinoma, Liver cancer
DURVALUMAB & TREMELIMUMAB

Approved



Australia
PBAC

Cancer
Endometrial cancer
DOSTARLIMAB

Not approved



France
HAS AP454

Cancer
Multiple myeloma
ELRANATAMAB

Approved



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Pharmacological Technologies



Wales
AWTTC 4197

Cancer
Colorectal cancer
FRUQUINTINIB

Not approved



Australia
PBAC

Cancer
Lung cancer
OSIMERTINIB

Not approved



Brazil
CONITEC

Cancer
Oesophageal cancer
NIVOLUMAB

Not approved



Wales
AWTTC OW29

Cancer
Colorectal cancer
PANITUMUMAB

Approved



Australia
PBAC

Cancer
Malignant melanoma
NIVOLUMAB & IPILIMUMAB

Approved



Scotland
SMC2812

Cancer
Pancreatic cancer
PEGYLATED LIPOSOMAL IRINOTECAN

Not approved



Brazil
CONITEC

Cancer
Oesophageal cancer
NIVOLUMAB & PEMBROLIZUMAB

Not approved



Germany
IQWiG A24-124

Cancer
Breast cancer
RIBOCICLIB

Not approved



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Pharmacological Technologies



Wales
AWTTC 5132

Cancer
Breast cancer
RIBOCICLIB
SUCCINATE

Not approved



Scotland
SMC2732

Cancer
Thyroid cancer
SELPERCATINIB

Approved with special conditions



Germany
IQWiG A24-128

Cancer
Lung cancer
TISLELIZUMAB

Approved with special conditions



England
NICE TA1072

Cancer
Lung cancer
TISLELIZUMAB

Terminated



Germany
IQWiG A24-129

Cancer
Oesophageal cancer
TISLELIZUMAB & CHEMOTHERAPY

Not approved



Wales
AWTTC 5431

Cancer
Lung cancer
TISLELIZUMAB

Not approved



Wales
AWTTC OW30

Cancer
Ovarian cancer
TRAMETINIB

Approved



Wales
AWTTC 5408

Cancer
Non-Hodgkin's lymphoma
ZANUBRUTINIB

Not approved

Pharmacological Technologies



Scotland
SMC2740

Cardiovascular
Atherosclerotic
cardiovascular disease
BEMPEDOIC ACID



England
NICE TA1066

Endocrine
Growth hormone
deficiency
SOMAPACITAN



Scotland
SMC2741

Cardiovascular
Atherosclerotic
cardiovascular disease
BEMPEDOIC ACID &
EZETIMIBE



Scotland
SMC2744

Eye
Age-related macular
degeneration
BEVACIZUMAB GAMMA



South Korea
HIRA 2025-88

Cardiovascular
Pulmonary hypertension,
Pulmonary arterial
hypertension
RIOCIGUAT



Australia
PBAC

Eye
Diabetic retinopathy
RANIBIZUMAB



Australia
PBAC

Endocrine
Type 2 diabetes
mellitus
PIOGLITAZONE



Australia
PBAC

Eye
Thyroid eye disease
TEPROTUMUMAB



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Pharmacological Technologies



South Korea
HIRA 2025-88

Gastrointestinal
Crohn's disease
INFLIXIMAB



Germany
IQWiG A25-42

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



South Korea
HIRA 2025-88

Gastrointestinal
Inflammatory bowel
disease
RAMOSETRON



Germany
IQWiG G25-13

Gastrointestinal
Primary biliary
cholangitis
SELADELPAR



Germany
IQWiG A25-40

Genetic & Metabolic
Amyloidosis
DARATUMUMAB +
VCD



England
NICE TA1078

Genetic & Metabolic
Molybdenum
cofactor deficiency
FOSDENOPTERIN



Germany
IQWiG G25-12

Genetic & Metabolic
Molybdenum
cofactor deficiency
FOSDENOPTERIN



Wales
AWTTC 4134

Genetic & Metabolic
Molybdenum cofactor
deficiency type A
FOSDENOPTERIN



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Pharmacological Technologies



Germany
IQWiG A25-41

Genetic & Metabolic
Hereditary
angioedema
GARADACIMAB



England
NICE TA1067

Genitourinary
Endometriosis
LINZAGOLIX



Argentina
IECS

Genetic & Metabolic
Acid sphingomyelinase
deficiency
OLIPUDASE ALFA



Germany
IQWiG A25-39

Genitourinary
Overactive bladder
VIBEGRON



Scotland
SMC2813

Genetic & Metabolic
Hyperarginaemia
PEGZILARGINASE



South Korea
HIRA 2025-88

Infection
Cytomegalovirus
GANCICLOVIR



Germany
IQWiG G25-10

Genetic & Metabolic
Obesity
SETMELANOTIDE



South Korea
HIRA 2025-88

Infection
Cytomegalovirus
LETERMOVIR



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Pharmacological Technologies



Brazil
CONITEC

Infection
Meningococcus
MENINGOCOCCAL B
VACCINE



South Korea
HIRA 2025-88

Musculoskeletal
Rheumatoid arthritis,
Juvenile arthritis
ETANERCEPT



Germany
IQWiG A25-33

Infection
Respiratory syncytial
virus
NIRSEVIMAB



Wales
AWTTC 6561

Musculoskeletal
Osteoporosis
TERIPARATIDE



France
HAS AP450

Mental Health
Post-partum
depression
ZURANOLONE



South Korea
HIRA 2025-88

Musculoskeletal
Rheumatoid arthritis, Juvenile
arthritis, Still's disease
TOCILIZUMAB



South Korea
HIRA 2025-88

Musculoskeletal
Rheumatoid arthritis,
Osteo-arthritis
ADALIMUMAB



Germany
IQWiG A25-38

Neurology
Migraine
ATOGEPAANT



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Pharmacological Technologies



Scotland
SMC2751

Neurology
Multiple sclerosis
CLADRIBINE



Australia
PBAC

Neurology
Multiple sclerosis
UBLITUXIMAB



England
NICE TA1069

Neurology
Myasthenia gravis
EFGARTIGIMOD



Scotland
SMC2756

Neurology
Migraine
SUMATRIPTAN



Australia
PBAC

Neurology
Sialorrhea
INCOBOTULINUMTOXINA



Scotland
SMC2750

Other
Graft-versus-host
disease
RUXOLITINIB



South Korea
HIRA 2025-88

Neurology
Narcolepsy
MODAFINIL



Brazil
CONITEC

Pregnancy
Contraception
ETONOGESTREL



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Pharmacological Technologies



Brazil
CONITEC

Pregnancy
Contraception
ETONOGESTREL

✓ **Approved**



Australia
PBAC

Pregnancy
Contraception
ETONOGESTREL WITH
ETHINYLESTRADIOL

✓ **Approved**



Australia
PBAC

Renal
Chronic kidney
disease
EMPAGLIFLOZIN

✓ **Approved**



Brazil
CONITEC

Renal
Haemolytic uraemic
syndrome
RAVULIZUMAB

✗ **Not**
approved



England
NICE TA1074

Renal
Nephropathy
SPARSENTAN

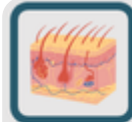
✓ **Approved**
with special
conditions



Australia
PBAC

Respiratory
Rhinosinusitis, Nasal
polyps
OMALIZUMAB

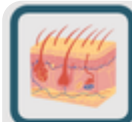
✓ **Approved**



South Korea
HIRA 2025-88

Skin
Psoriasis, Psoriatic
arthritis
APREMILAST

✓ **Approved**



Australia
PBAC

Skin
Hidradenitis
suppurativa
BIMEKIZUMAB

✓ **Approved**



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South Korea
HIRA 2025-88

Skin
Psoriasis
BIMEKIZUMAB



Approved



South Korea
HIRA 2025-88

Skin
Psoriasis
DEUCRAVACITINIB



Approved



Australia
PBAC

Skin
Psoriasis
GUSELKUMAB



Approved

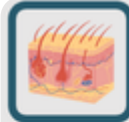


South Korea
HIRA 2025-88

Skin
Psoriasis, Psoriatic arthritis,
Palmoplantar pustulosis
GUSELKUMAB



Approved

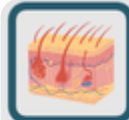


South Korea
HIRA 2025-88

Skin
Psoriasis, Psoriatic
arthritis
IXEKIZUMAB



Approved

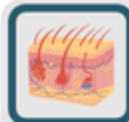


Wales
AWTTC 3715

Skin
Atopic dermatitis
NEMOLIZUMAB



Not
approved

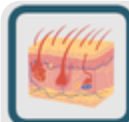


South Korea
HIRA 2025-88

Skin
Psoriasis, Psoriatic
arthritis
RISANKIZUMAB



Approved



South Korea
HIRA 2025-88

Skin
Psoriasis, Psoriatic
arthritis
SECUKINUMAB



Approved



Pharmacological Technologies



England
NICE TA1070

**Skin
Psoriasis
SPESOLIMAB**

✓ Approved
with special
conditions



South Korea
HIRA 2025-88

**Skin, Gastrointestinal
Psoriasis, Arthritis, Crohns
disease, Ulcerative colitis
USTEKINUMAB**

✓ Approved

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Non-pharmacological Technologies



Denmark
DCHQ

Cancer

Bladder cancer

HEXAMINOLEVULINATE
HYDROCHLORIDE-GUIDED
TRANSURETHRAL RESECTION



England
NICE IPG803

Gastrointestinal

**Gastroesophageal
reflux disease**

INACTIVE IMPLANT



Ireland
HIQA

Cancer

Cancer

MAGNETIC RESONANCE-
GUIDED RADIOTHERAPY



South Korea
NECA HTA-2025-16

Musculoskeletal

Disc herniation

AUTOLOGOUS PLATELET-
RICH PLASMA THERAPY



Denmark
DCHQ

Cardiovascular

Aneurysms

ENDOVASCULAR
REPAIR



Denmark
DCHQ

Musculoskeletal

Back pain

SELFBACK APP



England
NICE IPG805

Cardiovascular

Aortic valve regurgitation

TRANSCATHETER AORTIC
VALVE IMPLANTATION



South Korea
NECA Innovation-
2025-4

Neurology

Motor impairment

AI-BASED CUSTOMIZED
TRANSCRANIAL DIRECT
CURRENT STIMULATION



Non-pharmacological Technologies



England
NICE IPG804

Other
Pain

TARGETED MUSCLE
REINNERVATION



Germany
IQWiG H21-12

Surgery

Transplant

NORMOTHERMIC
LIVER PERFUSION



South Korea
HIRA 2025-92

Respiratory

Respiratory failure

DOUBLE-LUMEN
CANULA



South Korea
HIRA 2025-92

Surgery

Larynx disease, Lung disease, Oesophageal
disease, Stomach disease, Liver disease, Splenic
disease, Intestinal disease, Urological disease,
Uterine disease

REUSABLE AUTOMATIC
SUTURE DETACHABLE BODY



England
NICE HTE27

Skin

Ulcers

TOPICAL ANTIMICROBIAL
DRESSINGS



South Korea
HIRA 2025-92

Surgery

Cardiovascular surgery

GORE-TEX
CARDIOVASCULAR PATCH



Diagnostic Testing



South Korea
NECA HTA-2025-17

Cardiovascular
Thrombus formation
PLATELET
AGGREGATION ASSAY

 Not
approved

Other Guidance



**Scotland
SHGT**

Cardiovascular

Cardiac rhythm
abnormalities

**ELECTROCARDIOGRAM
(ECG) PATCH MONITORS**



**Evidence
review**



**Canada
INESSS**

Gastrointestinal

Dysphagia

**FLUOROSCOPIC OR
ENDOSCOPIC ASSESSMENT**



**Evidence
review**



**Sweden
SBU**

Neurology

Autism

**FOLIC ACID, OTHER B-
VITAMINS OR
MAGNESIUM**



**Evidence
review**



**Sweden
SBU**

Other

Opioid dependency

MAGNESIUM



**Evidence
review**



**Sweden
SBU**

Pregnancy

Infertility

**PREIMPLANTATION
GENETIC TESTING**



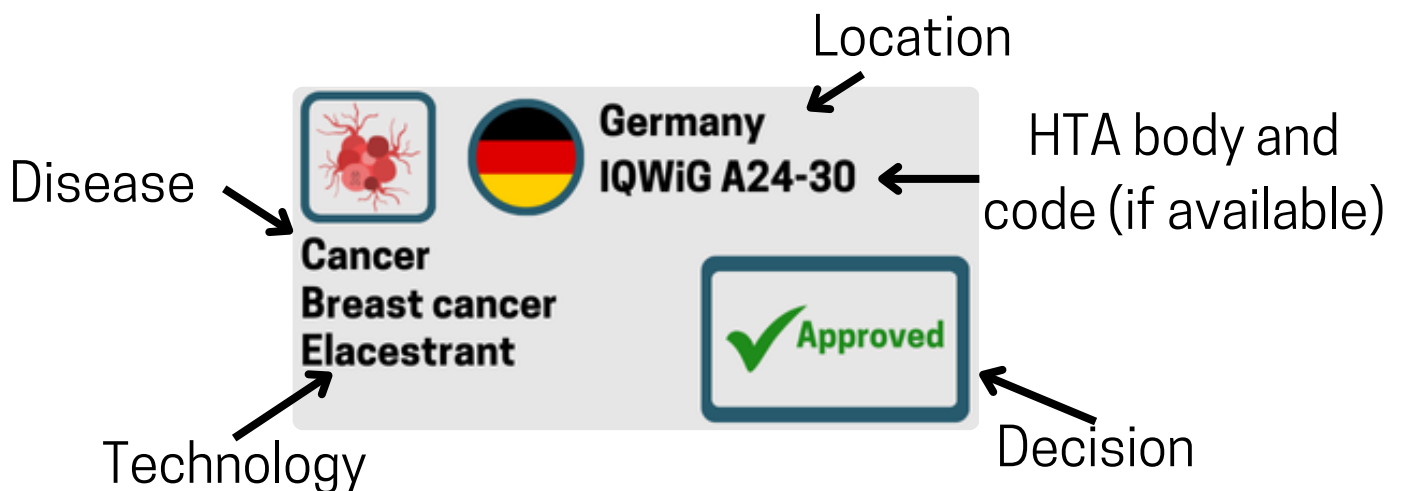
**Evidence
review**

HTANGEL

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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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