

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 25: May 2025

46% of approvals were cancer based submissions!

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

Good news for: **Erdafitinib**, approved for urothelial cancer in England and Scotland and excluded from assessment in Wales;
Nirmatrelvir plus ritonavir, approved for COVID-19 infection in Scotland and England; and **Cenobamate**, approved for focal-onset seizures in England.

Mixed news for: **Amivantamab**, approved in Germany as first-line therapy for advanced NSCLC in combination with Lazertinib, but not otherwise approved for use in NSCLC; **Donanemab**, not approved for Alzheimer's dementia in Scotland but excluded from assessment in Wales; and **Nintedanib**, not approved for fibrosing interstitial lung disease in Germany but approved in South Korea.

Bad news for: **Nimolizumab**, not approved in Germany for atopic dermatitis or prurigo nodularis; **Sarilumab**, not approved for polymyalgia rheumatica in Germany and Scotland; and patients with obesity and type 2 diabetes in Brazil, where **Semaglutide** and **Liraglutide** were not approved.

“

37 Approvals

18 with special arrangements
1 with orphan drug status

“

28 Not approved

8 Excluded

2 Terminated

“

12 Evidence reviews

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Pharmacological Technologies



Scotland
SMC2709

Blood
Beta-thalassaemia
EXAGAMGLOGENE
AUTOTEMCEL



Approved
orphan drug
status



Wales
AWMSG 6441

Cancer
Prostate cancer
ABIRATERONE



Approved



Germany
IQWiG A25-16

Blood
Haemophilia A
MARSTACIMAB



Not
approved



Argentina
IECS

Cancer
Chronic lymphocytic
leukaemia
ACALABRUTINIB



Not
approved



Germany
IQWiG A25-17

Blood
Haemophilia B
MARSTACIMAB



Not
approved



Argentina
IECS

Cancer
Chronic lymphocytic
leukaemia
ACALABRUTINIB WITH OR
WITHOUT OBINUTUZUMAB



Not
approved



Blood, Cancer,
Genetic & Metabolic,
Musculoskeletal,
Neurology, Renal



South Korea
HIRA 2025-73

Chronic lymphocytic leukaemia, Rheumatoid
arthritis, Wegener's granulomatosis and
microscopic polyangiitis, Treatment rejections,
Neuromyelitis optica, Autoimmune bullous
diseases, Autoimmune encephalitis, Nephrotic
syndrome
RITUXIMAB



Approved



Germany
IQWiG A25-08

Cancer
Lung cancer
AMIVANTAMAB



Approved
with special
conditions



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Pharmacological Technologies



Germany
IQWiG A25-10

Cancer
Lung cancer
AMIVANTAMAB



England
NICE TA1063

Cancer
Breast cancer
CAPIVASERTIB WITH
FULVESTRANT



Germany
IQWiG A25-09

Cancer
Lung cancer
AMIVANTAMAB



Wales
AWMSG 4016

Cancer
Lung cancer
CEMIPLIMAB



England
NICE TA1059

Cancer
Hodgkin lymphoma
BRENTUXIMAB
VEDOTIN



England
NICE TA1064

Cancer
Endometrial cancer
DOSTARLIMAB WITH
PLATINUM-BASED
CHEMOTHERAPY



Wales
AWMSG 4829

Cancer
Breast cancer
CAPIVASERTIB



Wales
AWMSG 5372

Cancer
Endometrial cancer
DURVALUMAB



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Pharmacological Technologies



England
NICE TA1062

Cancer
Urothelial cancer
ERDAFITINIB



Scotland
SMC2738

Cancer
Urothelial cancer
ERDAFITINIB



Wales
AWMSG 3787

Cancer
Urothelial cancer
ERDAFITINIB



Scotland
SMC2748

Cancer
Colorectal cancer
FRUQUINTINIB



Germany
IQWiG A25-20

Cancer
Multiple myeloma
ISATUXIMAB



Germany
IQWiG A25-11

Cancer
Lung cancer
LAZERTINIB



England
NICE TA1065

Cancer
Colorectal cancer
NIVOLUMAB PLUS
IPIILIMUMAB



England
NICE TA1060

Cancer
Lung cancer
OSIMERTINIB WITH
PEMETREXED AND PLATINUM-
BASED CHEMOTHERAPY



Pharmacological Technologies



Germany
IQWiG A24-110

Cancer
Cervical cancer
PEMBROLIZUMAB



Germany
IQWiG A25-43

Cancer
Cervical cancer
PEMBROLIZUMAB



Germany
IQWiG A25-27

Cancer
Lymphoma
PIRTOBRUTINIB



Germany
IQWiG A25-15

Cancer
Solid tumour
SODIUM
THIOSULFATE



Scotland
SMC2730

Cancer
Solid tumour
SODIUM
THIOSULFATE



England
NICE TA1068

Cancer
Oesophageal cancer
TISLELIZUMAB



Argentina
IECS

Cancer
Chronic lymphocytic
leukaemia
ZANUBRUTINIB



Wales
AWMSG 4635

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



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Pharmacological Technologies



England
NICE TA1061

Genetic & Metabolic
Friedreich's ataxia
OMAVELOXOLONE



Terminated



Brazil
CONITEC

Genitourinary
Endometriosis
ORAL
PROGESTOGENS



Approved
with special
conditions



Brazil
CONITEC

Genetic & Metabolic
Obesity
SEMAGLUTIDE



Not
approved



Infection



Brazil
CONITEC

Diphtheria, Tetanus, Acellular
pertussis, Hepatitis B,
Inactivated poliomyelitis 1/2/3,
Haemophilus influenzae B
ACELLULAR HEXAVALENT
VACCINE



Not
approved



Brazil
CONITEC

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



Not
approved



Germany
IQWiG A25-21

Infection
Human
immunodeficiency virus
CABOTEGRAVIR



Not
approved

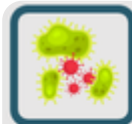


Brazil
CONITEC

Genitourinary
Endometriosis
LEVONORGESTREL-
RELEASING DEVICE



Approved



South Korea
HIRA 2025-73

Infection
Pseudomonas aeruginosa,
Bacterial endophthalmitis,
Pseudomonas aeruginosa,
Bacterial endophthalmitis
CEFTAZIDIME



Approved



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Pharmacological Technologies



Scotland
SMC2809

Infection

Human immunodeficiency virus
ELVITEGRAVIR/COBICISTAT/
EMTRICITABINE/TENOFOVIR
ALAFENAMIDE

Not approved



South Korea
HIRA 2025-73

Infection

Staphylococcus aureus
VANCOMYCIN

Approved with special conditions



Scotland
SMC2557

Infection

COVID-19
NIRMATRELVIR PLUS
RITONAVIR

Approved with special conditions



Wales
AWMSG 6440

Mental Health

Attention deficit hyperactivity disorder
GUANFACINE

Approved



England
NICE TA878

Infection

COVID-19
NIRMATRELVIR PLUS
RITONAVIR, SOTROVIMAB
AND TOCILIZUMAB

Approved with special conditions



Canada
INESSS REF1150

Mental Health

Depression
KETAMINE

Approved with special conditions



Germany
IQWiG A25-28

Infection

COVID-19
SIPAVIDART

Not approved



Germany
IQWiG A25-18

Musculoskeletal

Polymyalgia rheumatica
SARILUMAB

Not approved



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Pharmacological Technologies



Scotland
SMC2810

Musculoskeletal
Polymyalgia
rheumatica
SARILUMAB



South Korea
HIRA 2025-73

Neurology
Alzheimer's disease
DONEPEZIL



England
NICE TA753

Neurology
Epilepsy
CENOBAMATE



Brazil
CONITEC

Neurology
Plexiform
neurofibroma
SELUMETINIB



Scotland
SMC2687

Neurology
Alzheimer's disease
DONANEMAB



Wales
AWMSG 5385

Other
Chronic pain
ZICONOTIDE



Wales
AWMSG 5156

Neurology
Alzheimer's disease
DONANEMAB



Brazil
CONITEC

Pregnancy
Contraception
ETONOGESTREL-
RELEASING IMPLANT



Pharmacological Technologies



Brazil
CONITEC

Renal
Nephrotic syndrome
MYCOPHENOLATE
MOFETIL/
MYCOPHENOLATE SODIUM



Brazil
CONITEC

Renal
Nephrotic syndrome
RITUXIMAB



Wales
AWMSG 5248

Renal
Nephropathy
SPARSENTAN



Scotland
SMC2765

Respiratory
Allergic asthma
MEPOLIZUMAB



Germany
IQWiG A25-29

Respiratory
Interstitial lung
disease
NINTEDANIB



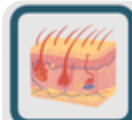
Germany
IQWiG A25-30

Respiratory
Progressive fibrosing
interstitial lung disease
NINTEDANIB



South Korea
HIRA 2025-73

Respiratory
Progressive fibrosing
interstitial lung disease
NINTEDANIB



Germany
IQWiG A25-32

Skin
Atopic dermatitis
NEMOLIZUMAB



Pharmacological Technologies



Germany
IQWiG A25-31

Skin
Prurigo nodularis
NEMOLIZUMAB

X Not approved



Wales
AWMSG 3148

Skin
Psoriasis
RIZANKIZUMAB

Hand Excluded

Non-pharmacological Technologies



South Korea
HIRA 2025-79

Cardiovascular
Stenosis, Restenosis
DRUG-ELUTING PTA
BALLON CATHETER



England
NICE HTE25

Neurology
Chronic tic disorders,
Tourette syndrome
DIGITAL THERAPY



England
NICE HTE26

Cardiovascular
Coronary artery disease
DRUG-ELUTING
STENTS



South Korea
HIRA 2025-77

Cardiovascular
Vascular intervention
HAEMOSTATIC-INVASIVE
HAEMOSTATIC DEVICES



Canada
INESSS REF1159

Eye
Glaucoma
MICROINVASIVE
SURGICAL DEVICES



Diagnostic Testing



England
NICE HTE24

Cancer
Skin cancer
AI TECHNOLOGIES

✓ Approved



Canada
INESSS REF1157

Cancer
Breast cancer
MULTI-GENE
EXPRESSION PROFILING
TESTS

✗ Not
approved



Canada
INESSS REF1155

Genetic & Metabolic
Congenital polymalformative
syndromes
NEXT GENERATION
SEQUENCING

✗ Not
approved



Canada
INESSS REF1152

Infection
Vancomycin-resistant
enterococcus
NUCLEIC ACID
AMPLIFICATION TESTS

✓ Approved

Other Guidance



USA
AHRQ

Cancer
Cancer
BLOOD-BASED TESTS



Evidence
review



Canada
CDA HC0100

Cardiovascular
Acute coronary syndrome,
Myocardial infarction
TROPONIN



Evidence
review



Canada
CDA HC0082

Cancer
Renal cancer
DRUGS FOR ADVANCED
RENAL CELLS CARCINOMA



Evidence
review



Scotland
SHTG

Endocrine
Type 2 diabetes
mellitus
DIGITAL DIABETES
PREVENTION PROGRAMMES



Evidence
review



Canada
CDA RC1551

Cancer
Laryngectomy
VOICE PROSTHESES AND
HEAT-MOISTURE
EXCHANGERS



Evidence
review



Canada
CDA OS0005

Endocrine
Type 2 diabetes
mellitus
OZEMPIC



Evidence
review



Canada
CDA RC1574

Cardiovascular
Cardiac arrest
AUTOMATED CHEST
COMPRESSION DEVICES



Evidence
review



Canada
CDA RD0073

Endocrine
Menopause
TRANSDERMAL AND ORAL
MENOPAUSAL HORMONE
THERAPY



Evidence
review

Other Guidance



Canada
INESSS REF442

Gastrointestinal
Peptic ulcer
PROTON PUMP
INHIBITORS



Evidence
review



Canada
INESSS REF1161

Infection
Diabetic foot
infection
ANTIBIOTIC THERAPY



Evidence
review



Canada
CDA RC1562

Infection
Influenza
ANTIVIRAL DRUGS



Evidence
review



USA
AHRQ

Pregnancy
Intrauterine growth
retardation
DIGESTIBLE
CARBOHYDRATE INTAKE



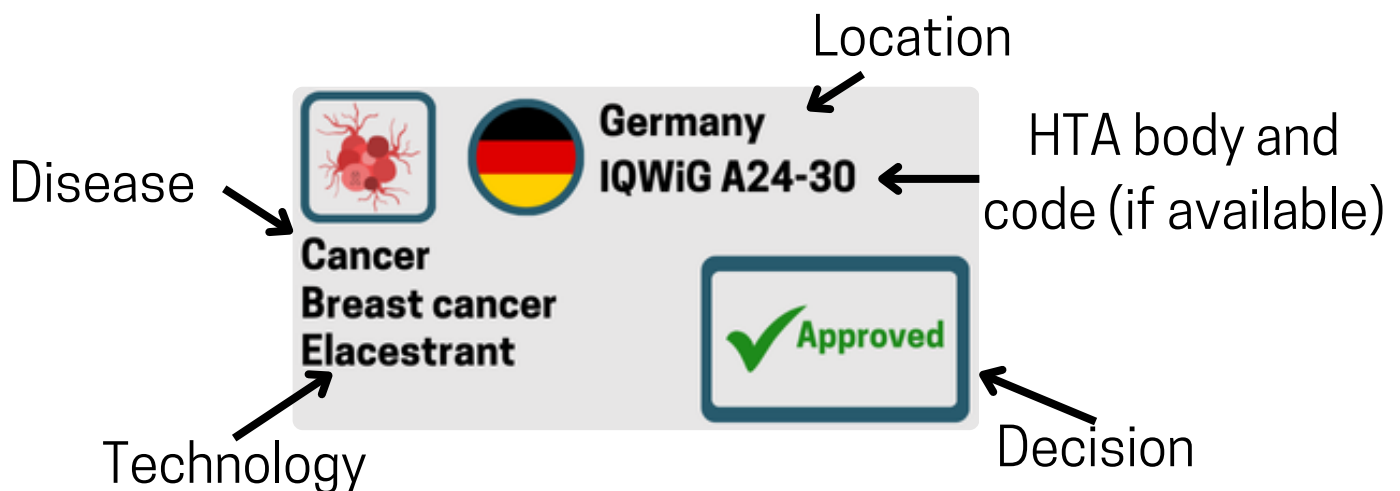
Evidence
review

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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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