

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 24: April 2025

32 approvals from Australia!

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

Good news for: **Capivasertib**, approved for PIK3CA/AKT1/PTEN-mutated, ER+, HER2-, locally advanced or metastatic breast cancer in Germany and Australia; **Elafibranor**, approved for primary biliary cholangitis in Scotland and Australia; and **Molnupiravir**, approved for mild to moderate COVID-19 in England and Scotland.

Mixed news for: **Bulevirtide**, approved for chronic hepatitis D in Germany but not in Australia; **Futibatinib**, approved for locally advanced or metastatic cholangiocarcinoma in Scotland but not in Australia; and **Lumasiran**, approved for primary hyperoxaluria in Australia but not Brazil; and **Tislelizumab**, not approved as first-line therapy for non-small cell lung cancer in England and Germany or for oesophageal, stomach and gastroesophageal junction cancer in Germany, but approved as second line therapy for PD-L1-negative NSCLC in Germany.

Bad news for: **Delgocitinib**, not approved for hand eczema in Germany; **Mavacamten**, not approved for hypertrophic obstructive cardiomyopathy in Argentina; and **Seladelpar**, not approved for primary biliary cholangitis in France.

“

66 Approvals

16 with special arrangements
4 with orphan drug status

“

50 Not approved

3 Excluded

2 Terminated

“

2 Evidence reviews

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Pharmacological Technologies



England
NICE TA1051

Blood
Haemophilia A
EFANESOCTOCOG
ALFA



Scotland
SMC2749

Cancer
Lung cancer
ALECTINIB



Germany
IQWiG G25-05

Blood
Sickle cell disease
EXAGAMGLOGEN
AUTOTEMCEL



Australia
PBAC

Cancer
Lung cancer
AMIVANTAMAB AND
LAZERTINIB



Germany
IQWiG G25-04

Blood
Beta-thalassaemia
EXAGAMGLOGEN
AUTOTEMCEL



Wales
AWTTC OW01

Cancer
Ovarian cancer, Fallopian tube
cancer, Peritoneal cancer
BEVACIZUMAB



Australia
PBAC

Blood
Polycythaemia vera
RUXOLITINIB



Canada
CDA RC1573

Cancer
Renal cancer
CABOZANTINIB



Pharmacological Technologies



Germany
IQWiG A25-26

Cancer
Breast cancer
CAPIVASERTIB



Australia
PBAC

Cancer
Multiple myeloma
DARATUMUMAB



Germany
IQWiG A24-105

Cancer
Breast cancer
CAPIVASERTIB



Australia
PBAC

Cancer
Bone cancer
DENOSUMAB



Australia
PBAC

Cancer
Breast cancer
CAPIVASERTIB



Australia
PBAC

Cancer
Neuroblastoma
EFLORNITHINE



Australia
PBAC

Cancer
Lung cancer
DABRAFENIB AND
TRAMETINIB



Australia
PBAC

Cancer
Breast cancer
ELACESTRANT



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Pharmacological Technologies



Australia
PBAC

Cancer
Multiple myeloma
ELRANATAMAB



Germany
IQWiG A25-01

Cancer
Urothelial cancer
ERDAFITINIB



Germany
IQWiG A24-98

Cancer
Urothelial cancer
ENFORTUMAB
VEDOTIN



Scotland
SMC2661

Cancer
Biliary tract cancer
FUTIBATINIB



Germany
IQWiG A25-22

Cancer
Urothelial cancer
ENFORTUMAB
VEDOTIN



Australia
PBAC

Cancer
Biliary tract cancer
FUTIBATINIB



Germany
IQWiG A24-108

Cancer
B-Cell Lymphoma
EPCORITAMAB



Australia
PBAC

Cancer
Cancer
GEMCITABINE



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Pharmacological Technologies



**Brazil
CONITEC**

**Cancer
Cancer
LAROTRECTINIB**

**Not
approved**



**Brazil
CONITEC**

**Cancer
Oesophageal cancer
NIVOLUMAB AND
PEMBROLIZUMAB**

**Not
approved**



**Australia
PBAC**

**Cancer
Systemic
mastocytosis
MIDOSTAURIN**

Approved



**Germany
IQWiG A25-03**

**Cancer
Lung cancer
OSIMERTINIB**

**Not
approved**



**Australia
PBAC**

**Cancer
Lymphoma
MOGAMULIZUMAB**

Approved



**Wales
AWTTC 5349**

**Cancer
Lung cancer
OSIMERTINIB**

Excluded



**Brazil
CONITEC**

**Cancer
Oesophageal cancer
NIVOLUMAB**

**Not
approved**



**England
NICE TA1052**

**Cancer
Pancreatic cancer
PEGYLATED LIPOSOMAL
IRINOTECAN**

Terminated



Pharmacological Technologies



Germany
IQWiG A25-23

Cancer
Urothelial cancer
PEMBROLIZUMAB



Germany
IQWiG A24-99

Cancer
Urothelial cancer
PEMBROLIZUMAB



Australia
PBAC

Cancer
Cervical cancer
PEMBROLIZUMAB



Australia
PBAC

Cancer
Breast cancer
PERTUZUMAB



Australia
PBAC

Cancer
Lymphoma
POLATUZUMAB
VEDOTIN



Brazil
CONITEC

Cancer
Gastrointestinal
stromal cancer
REGORAFENIB



England
NICE TA1055

Cancer
Ovarian cancer, Fallopian tube
cancer, Peritoneal cancer
RUCAPARIB



Australia
PBAC

Cancer
Breast cancer
SACITUZUMAB
GOVITECAN



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Pharmacological Technologies



France
HAS AP457

Cancer
Cancer
SODIUM
THIOSULFATE

 Not
approved



Brazil
CONITEC

Cancer
Prostate cancer
SUNITINIB

 Not
approved



Scotland
SMC2746

Cancer
Malignant melanoma
TEBENTAFUSP

 Not
approved



England
NICE TA1058

Cancer
Lung cancer
TISLELIZUMAB

 Terminated



Germany
IQWiG A24-129

Cancer
Oesophageal cancer
TISLELIZUMAB

 Not
approved



Germany
IQWiG A24-130

Cancer
Oesophageal cancer
TISLELIZUMAB

 Not
approved



Germany
IQWiG A24-127

Cancer
Lung cancer
TISLELIZUMAB

 Not
approved



Germany
IQWiG A24-126

Cancer
Lung cancer
TISLELIZUMAB

 Not
approved



Pharmacological Technologies



Germany
IQWiG A24-128

Cancer
Lung cancer
TISLELIZUMAB



Germany
IQWiG A24-131

Cancer
Stomach cancer,
Gastroesophageal junction
cancer
TISLELIZUMAB



Australia
PBAC

Cancer
Nasopharyngeal
cancer
TORIPALIMAB



Australia
PBAC

Cancer
Gastric cancer,
Gastroesophageal junction
cancer
ZOLBETUXIMAB



Brazil
CONITEC

Cardiovascular
Hereditary angioedema
HUMAN PLASMA-
DERIVED C1 ESTERASE
INHIBITOR



Argentina
IECS

Cardiovascular
Hypertrophic obstructive
cardiomyopathy
MAVACAMTEN



Brazil
CONITEC

Cardiovascular
Hyperlipidemia
ROSUVASTATIN



Australia
PBAC

Cardiovascular
Pulmonary
hypertension
SOTATERCEPT



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Pharmacological Technologies



Australia
PBAC

Endocrine
Menopause
FEZOLINETANT

Not
approved



Australia
PBAC

Gastrointestinal
Primary biliary
cholangitis
ELAFIBRANOR

Approved



Australia
PBAC

Endocrine
Hypoparathyroidism
PALOPEGTERIPARATIDE

Not
approved



Scotland
SMC2714

Gastrointestinal
Primary biliary
cholangitis
ELAFIBRANOR

Approved



Australia
PBAC

Eye
Macular oedema
FARICIMAB

Approved



Brazil
CONITEC

Gastrointestinal
Crohn's disease
INFLIXIMAB

Not
approved



Australia
PBAC

Eye
Thyroid eye disease
TEPROTUMUMAB

Not
approved



Australia
PBAC

Gastrointestinal
Familial progressive
cholestasis
ODEVIXIBAT

Not
approved

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Pharmacological Technologies



Brazil
CONITEC

Gastrointestinal
Exocrine pancreatic
insufficiency
PANCREATIN



Approved



France
HAS AP459

Gastrointestinal
Primary biliary cholangitis
SELADELPAR LYSINE
DIHYDRATE



Not
approved



Australia
PBAC

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



Approved



Australia
PBAC

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



Approved



Australia
PBAC

Gastrointestinal,
Musculoskeletal, Skin
Crohn's disease, Ulcerative
colitis, Psoriatic arthritis,
Psoriasis
USTEKINUMAB



Approved



France
HAS AP456

Genetic & Metabolic
Metachromatic
leukodystrophy
ATIDARSAGENE
AUTOEMCEL



Approved



England
NICE HST8

Genetic & Metabolic
X-linked
hypophosphataemia
BUROSUMAB



Approved
with special
conditions



Australia
PBAC

Genetic & Metabolic
Pompe disease
CIPAGLUCOSIDASE ALFA
AND MIGLUSTAT



Not
approved



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Pharmacological Technologies



Brazil
CONITEC

Genetic & Metabolic
Duchenne muscular dystrophy
DELANDISTROGEN
MOXEPARVOVEK

Not approved



France
HAS AP455

Genetic & Metabolic
Hypercholesterolaemia
EVINACUMAB

Approved



Australia
PBAC

Genetic & Metabolic
Cystic fibrosis
ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR

Approved



Australia
PBAC

Genetic & Metabolic
Cystic fibrosis
IVACAFTOR

Approved



Germany
IQWiG G25-01

Genetic & Metabolic
Gaucher's disease
ELIGLUSTAT

Approved orphan drug status



Argentina
IECS

Genetic & Metabolic
Hereditary angioedema
LANADELUMAB

Not approved



Scotland
SMC2755

Genetic & Metabolic
Amyloidosis
EPLONTERSEN

Approved



England
NICE HST33

Genetic & Metabolic
Activated phosphoinositide 3-kinase delta syndrome
LENIOLISIB

Approved with special conditions



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Pharmacological Technologies



Australia
PBAC

Genetic & Metabolic
Hyperoxaluria
LUMASIRAN



Approved



Brazil
CONITEC

Genetic & Metabolic
Hyperoxaluria
LUMASIRAN



Not
approved



England
NICE HST32

Genetic & Metabolic
Acid sphingomyelinase
deficiency
OLIPUDASE ALFA



Not
approved



Scotland
SMC2763

Genitourinary
Chronic kidney
disease
DAPAGLIFLOZIN



Approved
with special
conditions



Wales
AWTTC 4202

Genitourinary
Endometriosis
LINZAGOLIX



Excluded



England
NICE TA1057

Genitourinary
Endometriosis
RELUGOLIX-ESTRADIOL-
NORETHISTERONE



Approved



Germany
IQWiG G25-02

Infection
Hepatitis D
BULEVIRTIDE



Approved
orphan drug
status



Australia
PBAC

Infection
Hepatitis D
BULEVIRTIDE



Not
approved



Pharmacological Technologies



England
NICE TA1056

Infection
COVID-19
MOLNUPIRAVIR



Approved



Australia
PBAC

Neurology
Myasthenia gravis
EFGARTIGIMOD ALFA



Approved



Scotland
SMC2556

Infection
COVID-19
MOLNUPIRAVIR



Approved
with special
conditions



Brazil
CONITEC

Neurology
Multiple sclerosis
FINGOLIMOD
HYDROCHLORIDE



Not
approved



Brazil
CONITEC

Infection
Schistosomiasis
OXAMNIQUINE



Not
approved



Australia
PBAC

Neurology
Multiple sclerosis
NATALIZUMAB



Approved



England
NICE TA1053

Neurology
Multiple sclerosis
CLADRIBINE



Approved



Australia
PBAC

Neurology
Friedreich's ataxia
OMAVELOXOLONE



Not
approved

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Pharmacological Technologies



Australia
PBAC

Neurology
Myasthenia gravis
RAVULIZUMAB



Australia
PBAC

Neurology
Myasthenia gravis
ROZANOLIXIZUMAB



Australia
PBAC

Neurology
Myasthenia gravis
ZILUCOPAN



Germany
IQWiG A25-04

Other
Allergy
AR101



England
NICE TA1054

Other
Graft-versus-host
disease
RUXOLITINIB



Australia
PBAC

Pregnancy
Contraception
ESTETROL WITH
DROSPIRENONE



Australia
PBAC

Respiratory, Skin
Asthma, Atopic
dermatitis
DUPILUMAB



Australia
PBAC

Respiratory, Skin
Allergic asthma,
Urticaria
OMALIZUMAB



Pharmacological Technologies



Australia
PBAC

Respiratory, Skin
Allergic asthma,
Urticaria
OMALIZUMAB



Approved



Germany
IQWiG A24-107

Skin
Eczema
DELGOCITINIB



Not
approved

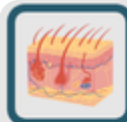


Scotland
SMC2698

Skin
Hidradenitis
suppurativa
BIMEKIZUMAB



Approved
with special
conditions



Wales
AWTTC 4765

Skin
Psoriasis
SPESOLIMAB



Excluded



Australia
PBAC

Skin
Dermatitis herpetiformis,
Leprosy, Actinomycotic
mycetoma
DAPSONE



Approved



Germany
IQWiG A25-37

Skin
Eczema
DELGOCITINIB



Not
approved

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Non-pharmacological Technologies



Brazil
CONITEC

Cardiovascular
Patent ductus arteriosus
PERCUTANEOUS CLOSURE DEVICE

X Not approved



Korea
NECA HTA-2025-15

Musculoskeletal
Osteoarthritis
POLYDIOXANONE SUTURE

X Not approved



Korea
NECA HTA-2025-14

Eye
Cataracts
PHOTOMODULATING
INTRAOCULAR LENS
IMPLANTATION AND
ULTRAVIOLET CONTROL

X Not approved



England
NICE IPG800

Pregnancy
Caesarean
BALLOON DISIMPACTION

✓ Approved with special conditions



Korea
NECA HTA-2025-11

Eye
Cataracts
PRECISION PULSE CAPSULOTOMY

✓ Approved



England
NICE HTE22

Surgery
Knee surgery, Hip replacement
ROBOT-ASSISTED SURGERY

✓ Approved with special conditions



Argentina
IECS

Mental Health, Neurology
Autism, Cerebral palsy
HIGH-TECH AUGMENTATIVE ALTERNATIVE COMMUNICATION SYSTEMS

X Not approved



England
NICE HTE21

Surgery
Soft tissue surgery
ROBOT-ASSISTED SURGERY

✓ Approved with special conditions



Diagnostic Testing



Korea
NECA HT-2025-12

Cancer
Cancer
DARATUMUMAB
INTERFERENCE REMOVAL
PROTEIN IMMUNOFIXATION
ELECTROPHORESIS ASSAY

 **Approved**



Korea
NECA **Innovation-**
2025-3

Cancer
Colorectal cancer
LIQUID BIOPSY TEST

 **Not**
approved



Korea
NECA HTA-2025-13

Neurology
Motor development delay
KOREAN VERSION OF ALBERTA
INFANT MOTOR
DEVELOPMENTAL SCALE

 **Not**
approved

Other Guidance



Canada
CDA RD0073

**Endocrine
Menopause
TRANSDERMAL MHT
VS ORAL MHT**



Evidence
review



Canada
CDA RD0074

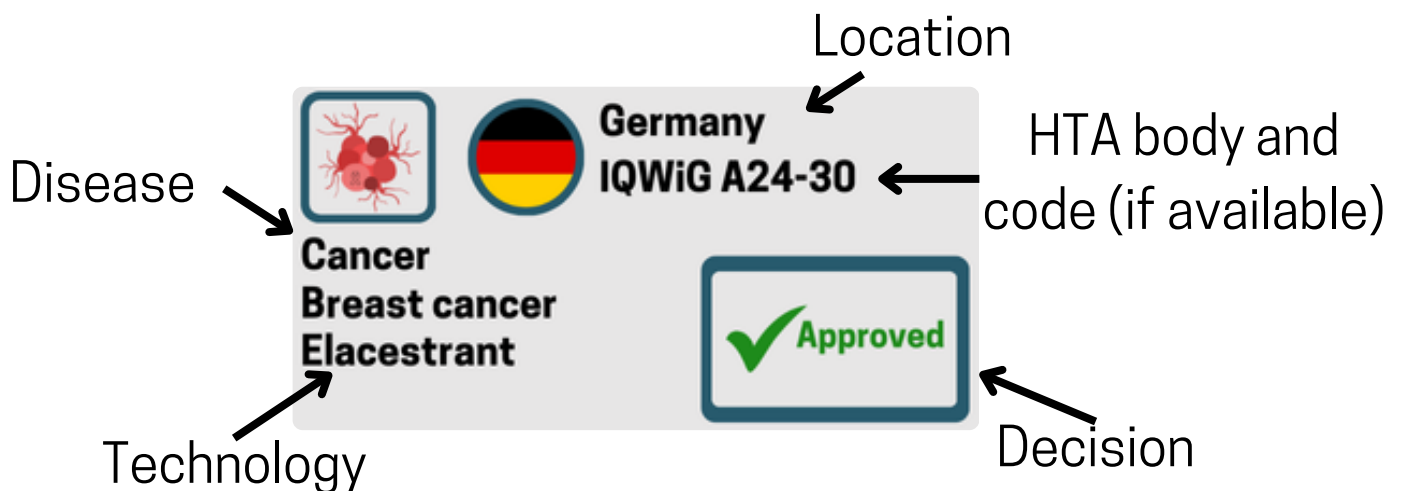
**Endocrine
Gender affirming care
TRANSDERMAL
OESTROGEN VS ORAL
OESTROGEN**



Evidence
review

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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