

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 15: July 2024

100% approval in genetic & metabolic conditions!

This newsletter summarises final decisions from HTA bodies around the world from published reports in July 2024.

Good news for:

Abrocitinib which was approved in approved in Australia for atopic dermatitis.

Etranacogene dezaparvovec which was approved for haemophilia B in England.

Ivacaftor-tezacaftor-elexacaftor, tezacaftor-ivacaftor and lumacaftor-ivacaftor was approved for the treatment of cystic fibrosis in England and Scotland.

Mixed news for:

Elranatamab was provisionally approved in Australia for multiple myeloma, but not approved in Germany for the same condition.

Nivolumab was approved in combination with relatlimab for melanoma in Wales, but not approved in Wales as monotherapy for oesophageal and gastric cancers.

Bad news for:

Trastuzumab deruxtecan was not approved in England for breast cancer and in Scotland for GEJ adenocarcinoma.

Ixekizumab was rejected twice in Brazil for the use in axial spondyloarthritis.

“

39 Approvals

10 with special arrangements

3 with orphan drug status

“

28 Not approved

4 Excluded submissions

4 Terminated submissions

“

9 Evidence reviews

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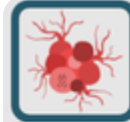
Pharmacological Technologies



England
NICE TA989

Blood

Moderately severe or
severe haemophilia B
Etranacogene
dezaparvovec



France
HAS AP346

Cancer

Lung cancer
Amivantamab



France
HAS AP322

Blood

Severe sickle cell
disease
Exagamglogene
autotemcel



Australia
TGA

Cancer

Multiple myeloma
Elranatamab



Brazil
CONITEC

Cancer

Prostate cancer
Abiraterone, apalutamide,
darolutamide, enzalutamide



Germany
IQWiG A24-12

Cancer

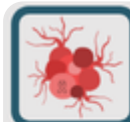
Multiple myeloma
Elranatamab



Brazil
CONITEC

Cancer

Prostate cancer
Abiraterone, apalutamide,
darolutamide, enzalutamide



Wales
AWTTC 4998

Cancer

Advanced
cholangiocarcinoma
Futibatinib



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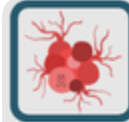
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Pharmacological Technologies



France
HAS AP360

Cancer
Diffuse large B-cell
lymphoma
Glofitamab



Argentina
IECS

Cancer
Gastropancreatic
neuroendocrine tumors
Lutetium-177



Germany
IQWiG A24-35

Cancer
Multiple myeloma
Idecabtagene
vicleucel



Wales
AWTTC OW28

Cancer
Oesophageal and
gastric cancer
Nivolumab



England
NICE TA987

Cancer
B-cell non-Hodgkin
lymphoma
Lisocabtagene
maraleucel



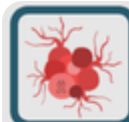
Scotland
SMC 2645

Cancer
Advanced Melanoma
Nivolumab/
relatlimab



Australia
TGA

Cancer
Prostate Cancer
Lutetium (177Lu)
vipivotide tetraxetan



Brazil
CONITEC

Cancer
Newly advanced
ovarian cancer
Olaparib



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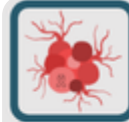
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Pharmacological Technologies



Scotland
SMC 2660

Cancer
Gastric or GEJ
adenocarcinoma
Pembrolizumab



Germany
IQWiG A24-65

Cancer
Multiple myeloma
Talquetamab



Scotland
SMC 2644

Cancer
Gastric or GEJ
adenocarcinoma
Pembrolizumab



Australia
TGA

Cancer
Oesophageal squamous
cell carcinoma, Non-
small cell lung cancer
Tislelizumab



Wales
AWTTC 3502

Cancer
Prostate Cancer
Relugolix



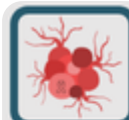
England
NICE TA992

Cancer
Breast cancer
Trastuzumab
deruxtecan



France
HAS AP348

Cancer
Advanced medullary
thyroid cancer
Selpercatinib



Scotland
SMC 2693

Cancer
Gastric or GEJ
adenocarcinoma
Trastuzumab deruxtecan



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Pharmacological Technologies



Brazil
CONITEC

Cardiovascular
Pulmonary arterial
hypertension
Riociguat

Not
approved



Scotland
SMC 2641

Eye
Retinal dystrophy
Voretigene
neparvovec

Approved
orphan drug
status



England
NICE TA990

Cardiovascular
Acute ischaemic
stroke
Tenecteplase

Approved



Germany
IQWiG A24-42

Gastrointestinal
Moderate to severe
activeulcerative colitis
Etrasimod

Not
approved



Argentina
IECS

Eye
Diabetic
maculopathy
N/A

Not
approved



Australia
TGA

Genetic & Metabolic
Type 1 & type 2
diabetes
Insulin icodec

Approved



Argentina
IECS

Eye
Age-related macular
degeneration
N/A

Not
approved



Scotland
SMC 2713

Genetic & Metabolic
Cystic fibrosis
Ivacaftor-tezacaftor-
elexacaftor

Approved



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Pharmacological Technologies



England
NICE TA988

Genetic & Metabolic
Cystic fibrosis
Ivacaftor-tezacaftor-
elixacaftor, tezacaftor-
ivacaftor and lumacaftor-
ivacaftor

✓ Approved
with special
conditions



Australia
TGA

Genetic & Metabolic
Amyloidosis
Vutrisiran

✓ Approved



Scotland
SMC 2712

Genetic & Metabolic
Cystic fibrosis
Lumacaftor-ivacaftor

✓ Approved



France
HAS AP357

Infection
Serious infections
Aztreonam/
avibactam

✓ Approved



Scotland
SMC 2665

Genetic & Metabolic
Fabry disease
Pegunigalsidase alfa

✓ Approved
with special
conditions



Brazil
CONITEC

Infection
Cytomegalovirus
Ganciclovir,
valganciclovir

✓ Approved



Scotland
SMC 2711

Genetic & Metabolic
Cystic fibrosis
Tezacaftor-ivacaftor

✓ Approved



Brazil
CONITEC

Infection
Cytomegalovirus
Ganciclovir,
valganciclovir

✗ Not
approved



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Pharmacological Technologies



Ireland
HIQA

Infection
Shingles
Herpes Zoster
vaccination

Not
approved



Germany
IQWiG A24-41

Musculoskeletal
Moderate to severe
active ulcerative colitis
Abaloparatide

Not
approved



Scotland
SMC 2691

Infection
Multidrug resistant
HIV-1
Lenacapavir

Terminated



Brazil
CONITEC

Musculoskeletal
Axial
spondyloarthritis
Ixekizumab

Not
approved



Brazil
CONITEC

Infection
Cytomegalovirus
Maribavir

Not
approved



Brazil
CONITEC

Musculoskeletal
Axial
spondyloarthritis
Ixekizumab

Not
approved



Germany
IQWiG A24-27

Infection
RSV diseases
Nirsevimab

Not
approved



Germany
IQWiG A24-36

Neurology
Generalised
myasthenia gravis
Efgartigimod alfa

Not
approved



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Pharmacological Technologies



Brazil
CONITEC

Neurology

Transthyretin-associated
familial amyloidotic
polyneuropathy
Inotersen



Excluded



Scotland
SMC 2642

Renal

Chronic kidney
disease
Empagliflozin



Approved
with special
conditions



Wales
AWTTC 3708

Other

Smoking cessation
Cytisinicline



Approved



Australia
TGA

Renal

Primary
hyperoxaluria type 1
Lumasiran



Approved



Scotland
SMC 2670

Pregnancy

Assisted reproductive
technology
Follitropin delta



Approved
with special
conditions



Australia
TGA

Skin

Atopic dermatitis
Abrocitinib



Approved



Australia
TGA

Pregnancy

Contraception
Levonorgestrel



Approved



England
NICE TA986

Skin

Moderate to severe
atopic dermatitis
Lebrikizumab



Approved
with special
conditions



Pharmacological Technologies



**Brazil
CONITEC**

**Skin
Atopic dermatitis
Mometasone furoate**



Excluded



**Scotland
SMC 2692**

**Surgery
General anaesthesia
Remimazolam**



Terminated



**Australia
TGA**

**Skin
Glabellar and lateral
canthal lines
RelabotulinumtoxinA**



Approved



**Australia
TGA**

**Skin
Severe alopecia
areata
Ritlecitinib**



Approved



**Brazil
CONITEC**

**Skin
Atopic dermatitis
Tacrolimus**



**Not
approved**

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Non-pharmacological Technologies



Argentina
IECS

Cancer
Cancer
Proton radiotherapy

 **Not approved**



Argentina
IECS

Other
Cow's milk protein
allergy
Partially hydrolyzed milk
formula

 **Not approved**



England
NICE TA985

Cancer
Advanced hepatocellular
carcinoma
Radiation therapy with
QuiremSpheres

 **Approved**
with special
conditions



South Korea
NECA PV-2024-4

Surgery
Spinal surgery
Screw insertion

 **Approved**



Argentina
IECS

Cancer
Bladder tumours
Transurethral
resection

 **Not approved**



Germany
IQWiG N23-02

Musculoskeletal
Anterior cruciate
ligament ruptures
Active knee motion
splints

 **Not approved**



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Diagnostic Testing



England
NICE DG59

Cardiovascular
Ischaemic stroke or
transient ischaemic attack
CYP2C19 genotype
testing



South Korea
NECA HTA-2024-31

Infection
Typhus
PCR



Germany
IQWiG A24-37

Cardiovascular
Blood/brain barrier
and/or vascular
abnormalities
Gadopichlenol



Brazil
CONITEC

Infection
Meningitis and
encephalitis
Rapid direct multiplex
PCR test



South Korea
NECA PV-2024-7

Eye
Eye disease
Artificial Intelligence



South Korea
NECA HTA-2024-29

Other
Hearing loss
Eustachian Tube
Function Test



South Korea
NECA HTA-2024-30

Gastrointestinal
Gastroesophageal
reflux disease
Mucosal Impedance



South Korea
NECA PV-2024-9

Surgery
Aortic dissection
Artificial Intelligence



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Other Guidance



Switzerland
FOPH

Cancer
Blood and lymph
node cancer
CAR-T cells



Evidence
review



Canada
CADTH HC0068-000

Genetic & Metabolic
Growth hormone
deficiency, idiopathic short
stature, Turner syndrome
Somatropin



Evidence
review



Switzerland
FOPH

Cancer
Breast cancer
Trastuzumab



Evidence
review



USA
AHRQ

Mental Health
Maternal mental health
Cognitive behavioral therapy,
interpersonal therapy,
behavioural activation,
exercise interventions,
specific acupuncture



Evidence
review



Switzerland
FOPH

Cancer
Glioblastoma
Tumour therapy
fields



Evidence
review



Switzerland
FOPH

Musculoskeletal
Knee or hip
osteoarthritis
Glucocorticoid



Evidence
review



Canada
CADTH HC0063-000

Gastrointestinal
Crohn disease,
ulcerative colitis
N/A



Evidence
review



Canada
CADTH RC1542-000

Other
Hearing loss
Auditory verbal
therapy



Evidence
review



Other Guidance



Canada
CADTH RE0045-000

Other
Chronic noncancer
pain
N/A

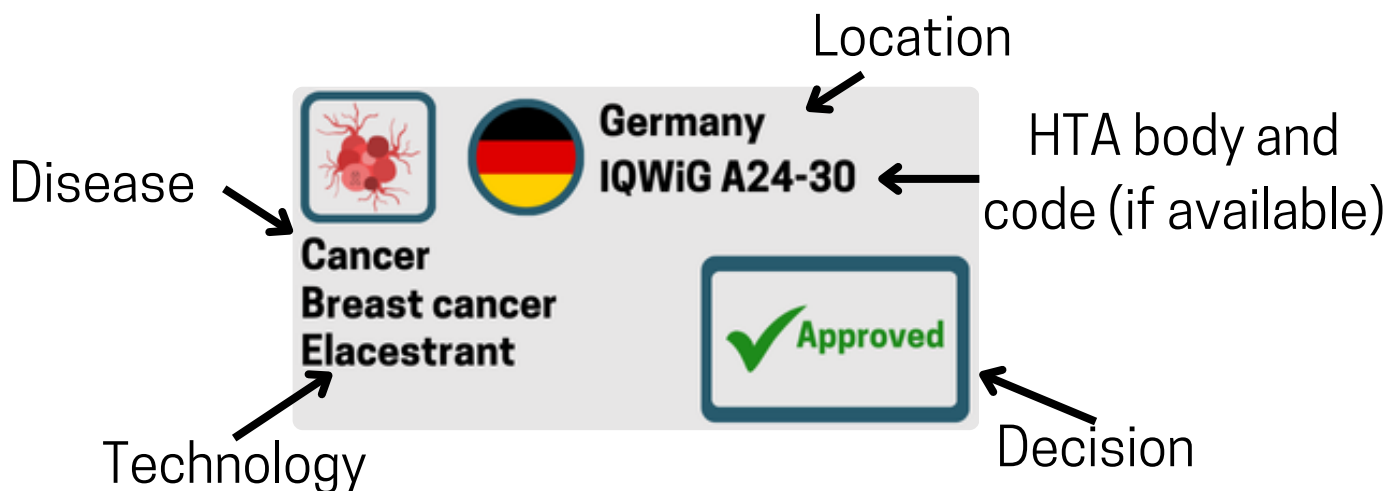


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Further Information

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.



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