

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 14: June 2024

Approval decisions are split almost 50:50!

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

Good news for:

Etrasimod, approved for ulcerative colitis in Australia and Scotland; **Ivosidenib**, approved for acute myeloid leukaemia in England and France; **Voxelotor**, approved for haemolytic anaemia in England and sickle cell disease in Scotland.

Mixed news for:

Capivasertib, approved for breast cancer in Australia but not in France; **Dupilumab**, approved in France for prurigo nodularis but not approved in Scotland for eosinophilic esophagitis.

Bad news for:

Nivolumab, not approved for malignant melanoma in England and non-small-cell lung cancer in France; **Pembrolizumab**, not approved for stomach or gastroesophageal junction cancer in England and Germany and not approved for biliary tract carcinoma in Scotland; **Polatumab vedotin**, not approved alone or with rituximab, cyclophosphamide, doxorubicin and prednisone for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in Germany.

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32 Approvals

8 with special arrangements
1 with orphan drug status

“

31 Not approved

7 Excluded submissions

“

5 Evidence reviews

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Pharmacological Technologies

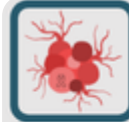


Wales
AWTTC 3953

Blood
Hemophilia B
Etranacogene
dezaparvovec



Excluded



Brazil
CONITEC

Cancer
Myelodysplastic
syndrome
Azacitidine



Approved



Scotland
SMC2636

Blood
Anaemia
Momelotinib



Approved



France
HAS AP345

Cancer
Breast cancer
Capivasertib



Not
approved

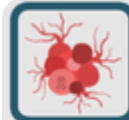


England
NICE TA981

Blood
Haemolytic anaemia
Voxelotor



Approved
with special
conditions



Australia
TGA L01EX27

Cancer
Breast cancer
Capivasertib



Approved



Scotland
SMC2626

Blood
Sickle cell disease
Voxelotor



Approved
with special
conditions



Scotland
SMC2681

Cancer
Acute myeloid leukaemia
Decitabine and
cedazuridine



Not
approved



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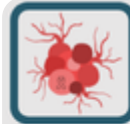
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Pharmacological Technologies



Germany
IQWiG A24-29

Cancer
Acute myeloid leukaemia
Decitabine/
cedazuridine



Scotland
SMC2614

Cancer
Relapsed or refractory
diffuse large B-cell
lymphoma (DLBCL)
Glofitamab



Germany
IQWiG A23-143

Cancer
Endometrial cancer
Dostarlimab



England
NICE TA979

Cancer
Acute myeloid leukaemia
Ivosidenib



Wales
AWTTC 4943

Cancer
Relapsed or refractory
multiple myeloma
Elranatamab



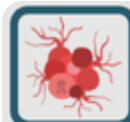
France
HAS A24-01

Cancer
Acute myeloid leukaemia
Ivosidenib



Scotland
SMC2632

Cancer
Relapsed or refractory
diffuse large B-cell
lymphoma (DLBCL)
Epcoritamab



Brazil
CONITEC

Cancer
Lymphoma
Lenalidomide with
rituximab



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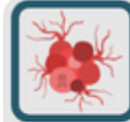
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Australia
TGA L01BB07

Cancer
T-ALL and T-LBL
Nelarabine



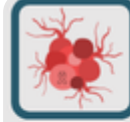
England
NICE TA983

Cancer
Stomach or
gastroesophageal
junction cancer
Pembrolizumab



England
NICE TA980

Cancer
Melanoma
Nivolumab



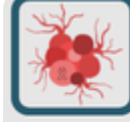
Scotland
SMC2683

Cancer
Biliary tract
carcinoma
Pembrolizumab



France
HAS A23-141

Cancer
Non-small cell lung
cancer
Nivolumab



Germany
IQWiG A24-01

Cancer
Stomach or
gastroesophageal
junction cancer
Pembrolizumab



Austria
AIHTA 178

Cancer
Advanced non-small
cell lung cancer
Osimertinib



Germany
IQWiG A24-58

Cancer
Stomach or
gastroesophageal
junction cancer
Pembrolizumab



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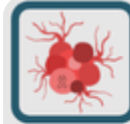
Pharmacological Technologies



Brazil
CONITEC

Cancer

Breast cancer
Pertuzumab and
trastuzumab (fixed-dose
subcutaneous)



Brazil
CONITEC

Cancer

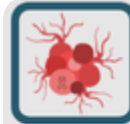
Thyroid cancer
Recombinant TSH



Brazil
CONITEC

Cancer

Breast cancer
Pertuzumab and
trastuzumab (fixed-dose
subcutaneous)



Brazil
CONITEC

Cancer

Lymphoma
Rituximab
(monotherapy)



Germany
IQWiG A23-141

Cancer

Relapsed or refractory
diffuse large B-cell
lymphoma (DLBCL)
Polatumab vedotin



Wales
AWTTC 5155

Cancer

Ovarian Cancer
Rucaparib



Germany
IQWiG A24-60

Cancer

Relapsed or refractory
diffuse large B-cell
lymphoma (DLBCL)
Polatumab vedotin



Brazil
CONITEC

Cancer

Thyroid cancer
Sorafenib and
lenvatinib



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Pharmacological Technologies



Austria
AIHTA 177

Cancer
Metastatic
non-small-cell lung
cancer (NSCLC)
Sugemalimab



Wales
AWTTC 5341

Cardiovascular
Acute ischaemic
stroke
Tenecteplase



Austria
AIHTA 179

Cancer
Locally advanced or
metastatic non-small
cell lung cancer
Tislelizumab



Australia
TGA L04AE

Gastrointestinal
Ulcerative colitis
Etrasimod



Germany
IQWiG A24-25

Cardiovascular
Heart failure
Enalapril



Scotland
SMC2682

Gastrointestinal
Eosinophilic esophagitis
Dupilumab



England
NICE TA984

Cardiovascular
Transthyretin
amyloidosis with
cardiomyopathy
Tafamidis



Scotland
SMC2655

Gastrointestinal
Ulcerative colitis
Etrasimod



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Pharmacological Technologies



Wales
AWTTC 4751

Genitourinary
Uterine fibroids
Linzagolix



Excluded



Switzerland
FOPH

Metabolic/ genetic
Cystic fibrosis
Elxacaftor/
tezacaftor/ ivacaftor



Not
approved



Germany
IQWiG A23-139

Infection
Cytomegalovirus
Letermovir



Approved



France
HAS A24-59

Metabolic/ genetic
Acid sphingomyelinase
deficiency
Olipudase alfa



Approved



Germany
IQWiG A24-27

Infection
Respiratory syncytial
virus
Nirsevimab



Not
approved



Germany
IQWiG G24-06

Metabolic/ genetic
Friedreich's ataxia
Omaveloxolone



Approved
orphan drug
status



Argentina
IECS

Infection
Dengue fever
Quadrivalent dengue
vaccine



Not
approved



Scotland
SMC2653

Metabolic/ genetic
Obesity
Tirzepatide



Approved
with special
conditions



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Pharmacological Technologies



England
NICE TA982

Musculoskeletal
Idiopathic arthritis
Baricitinib



Germany
IQWiG G24-05

Neurology
Generalized
myasthenia gravis
Rozanolixizumab



Wales
AWTTC 5094

Musculoskeletal
Idiopathic arthritis
Baricitinib



Canada
CADTH RC1534-000

Neurology
Cytokine release syndrome
Neurotoxicity syndrome
Tocilizumab, anakinra,
siltuximab



Scotland
SMC2680

Musculoskeletal
Focal spasticity
Clostridium botulinum
neurotoxin type A



Germany
IQWiG A24-26

Neurology
Generalized
myasthenia gravis
Zilucoplan



Canada
CADTH RC1540-000

Neurology
Multiple sclerosis and
clinically isolated syndrome
Interferons, glatiramer
acetate, and minocycline



Germany
IQWiG A24-24

Other
Insomnia
Daridorexant



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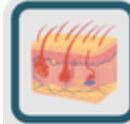
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Pharmacological Technologies



Brazil
CONITEC

Other
Neuromyelitis optica
spectrum disorder
Inebilizumab



France
HAS AP240

Skin
Prurigo nodularis
Dupilumab



Canada
CADTH RC1536-000

Other
Therapy-related
toxicities
Infliximab



Australia
TGA D11AH

Skin
Atopic dermatitis
Lebrikizumab



Canada
CADTH RC1539-000

Other
Chronic non-cancer
pain
Nabilone



Wales
AWTTC 5025

Skin
Vitiligo
Ruxolitinib



Canada
RC1531-000

Pregnancy
Fetal alcohol spectrum
disorder
Choline supplementation



France
HAS AP356

Skin
Multiple myeloma
Talquetamab



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Non-pharmacological Technologies



Switzerland
FOPH

Cancer
Glioblastoma
Tumour treating fields



Evidence
review



South Korea
NECA HTA-2024-24

Musculoskeletal
Knee osteoarthritis
Autologous fat-derived stromal vascular fraction treatment



Approved
with special
conditions



Brazil
CONITEC

Cardiovascular
Left ventricular heart failure
Left ventricular assist device



Not
approved



England
NICE IPG789

Musculoskeletal
Hallux valgus
Minimally invasive percutaneous surgical techniques



Approved



South Korea
NECA Innovation-2024-6

Cardiovascular
Stroke
Virtual reality-based software for visual perception training



Approved



Germany
IQWiG E20-06

Musculoskeletal
Drug-resistant epilepsy
Transcutaneous vagus nerve stimulation



Evidence
review



Germany
N23-02

Musculoskeletal
Ligament ruptures
Active knee movement splints



Evidence
review



South Korea
NECA Innovation-2024-5

Respiratory
COPD
Respiratory rehabilitation software



Approved



Non-pharmacological Technologies



Argentina
IECS

Surgery
Urological pathology
Balloon dilation with
paclitaxel



Not
approved

Diagnostic Testing



Spain
AQUAS

Cancer
Breast Cancer
Support tool in
ultrasound



Other Guidance



Canada
CADTH HC0078-000

Other
Various
Minimum Retesting
Intervals

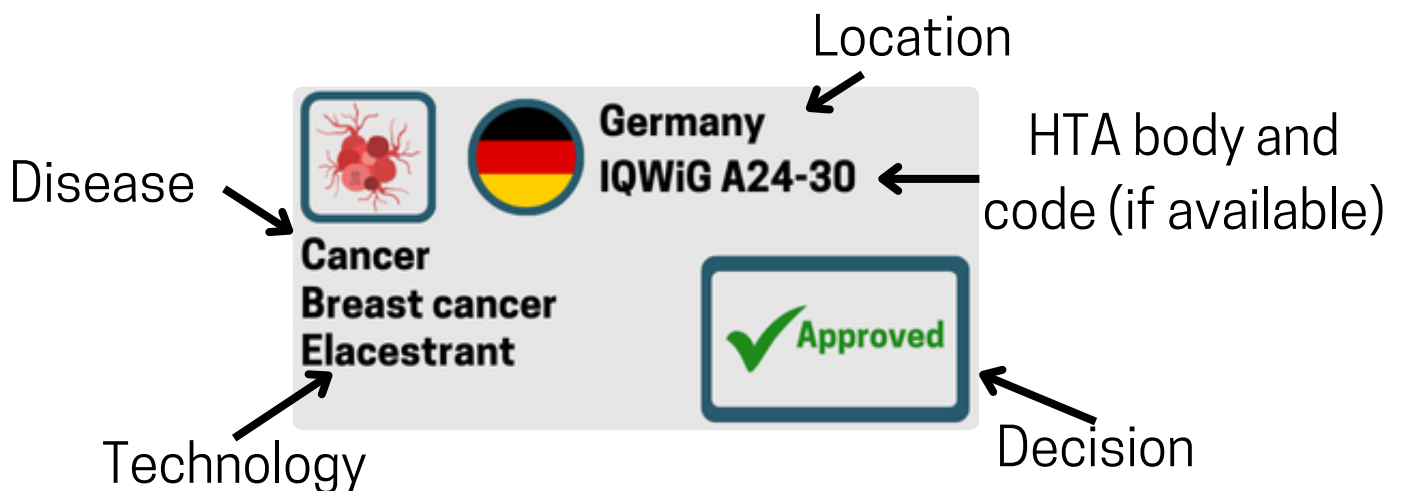


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Further Information

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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