

This newsletter summarises final decisions from HTA bodies around the world from August 2023.

These decisions have been categorised into one of four groups. You can click on the category you are interested in to jump to that section.

[Pharmacological Technologies](#)

[Non-pharmacological Technologies](#)

[Diagnostic Tests](#)

[Other Guidance](#)

Within each section the reports have been grouped according to clinical speciality. On the section contents page, there are shortcuts to each clinical speciality and specific report. All tiles are hyperlinked to the report file or to the HTA website.

Here we list a key for the decisions made by the HTA bodies for the reports listed in this newsletter.



Approved - This is where the reporting document states that the technology has been approved.



Not approved - This is where the reporting document states that the technology has not been approved.



Terminated - The report was terminated, additional details are provided under the icon.



Excluded - The report was excluded because it is covered by another HTA body in that country.



Unclear - This is where documentation cannot be translated or it is unclear on the reporting outcome.



Note - This entry includes a note from the report relating to the technology.



Evidence review - This is for reports that do not report a decision but summarises the evidence for the technology.

Pharmacological Technologies



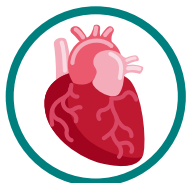
Blood

- Emicizumab - Brazil
- Emicizumab - Brazil
- Alfalonoctocog - Brazil
- Enoxaparin sodium - Australia
- Etranacogen dezaparvovec - Germany
- Luspatercept - Germany



Cancer

- Glofitamab - Australia
- ¹⁷⁷Lu - France
- Trastuzumab deruxtecan - France
- Cemiplimab - Germany
- Cemiplimab - Germany
- Sotorasib - Germany
- Tremelimumab - Germany
- Durvalumab - Germany
- Loncastuximab tesirine - Germany
- Luspatercept - Germany



Cardiovascular

- Icosapent ethyl - Scotland
- Dapagliflozin - Scotland



Eye

- Ravulizumab - France
- Aflibercept - Scotland
- Intravitreal dexamethasone implant - Brazil

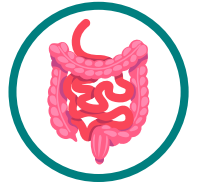
- Upadacitinib - Germany
- Mirikizumab - Wales

- Finerenone - Germany
- Finerenone - Germany

- Tixagevimab/cilgavimab - Germany

- Combination of cipaglifosidase alfa and miglustat - France
- Setmelanotide - France
- Combination of cipaglifosidase alfa and miglustat - England
- Setmelanotide - Germany
- Pegunigalsidase alfa - Wales

- Rimegepant (as sulfate) - Australia



Gastrointestinal



Genitourinary



Infection



Metabolic
/Genetic



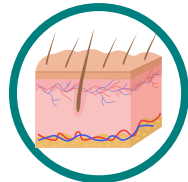
Neurology

Pharmacological Technologies



Respiratory

- Elexacaftor/tezacaftor/ivacaftor - Brazil
- Tezepelumab- Scotland



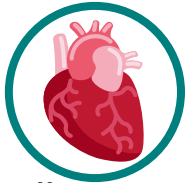
Skin

- Baricitinib - Scotland

Other

- Selumetinib - Scotland
- Dermatophagoides pteronyssinus and Dermatophagoides farina - Scotland

Non-pharmacological Technologies



Cardiovascular

- Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium - England



Mental health

- Cognitive Behaviour Therapy using digital treatment devices - South Korea

Diagnostic Tests



Infection

- [Genedrive MT-RNR1 ID Kit - England](#)



Cancer

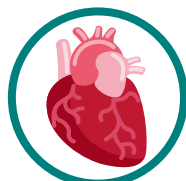
- [Quantitative faecal immunochemical testing - England](#)

Other Guidance



Cancer

- [Crisantaspase - Austria](#)
- [Cedazuridine/decitabine - Austria](#)
- [Elacestrant - Austria](#)
- [Talquetamab - Austria](#)
- [Epcoritamab - Austria](#)
- [Tislelizumab - Austria](#)
- [Nivolumab - Austria](#)
- [Pembrolizumab - Austria](#)
- [PSMA-targeted radiopharmaceuticals - Canada](#)
- [Radiotherapy - United States](#)



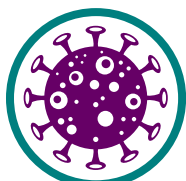
Cardiovascular

- [Transcatheter Edge-To-Edge Valve Repair - Canada](#)
- [Surgical procedures - Switzerland](#)
- [Dapagliflozin - Germany](#)
- [Dapagliflozin - Germany](#)



Endocrine

- [Somatotropin - Canada](#)



Infection

- [RSVpreF vaccine - Canada](#)
- [Standard quadrivalent influenza vaccination - Ireland](#)
- [Meningococcal ACWY vaccine - Norway](#)

- [Somatotropin - Canada](#)
- [Lipid panel screening - Canada](#)



Metabolic /Genetic

- [Transcutaneous non-invasive vagus nerve stimulation - Norway](#)



Neurology

- [Triclosan-coated sutures - Norway](#)

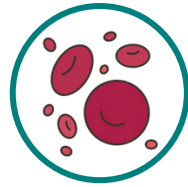


Surgery

- [At-Home polysomnography - Canada](#)
- [Opioid agonists - Canada](#)
- [Cannabis and other plant-based treatments - United States](#)
- [Personalised precision medicine - Spain](#)

Other

Pharmacological Technologies



Blood

Brazil



Alfalonoctocog

Secondary prophylaxis for hemophilia A previously treated and without inhibitor

CONITEC



Population:
Other
Adult and adolescents 12 years and over
02 August 2023

Brazil



Emicizumab

Population:
Other
No age restriction, except those undergoing immunosuppressive therapy

02 August 2023

Prophylactic treatment of patients with moderate to severe hemophilia A and Factor VIII inhibitory antibodies

CONITEC



Brazil



Emicizumab

Prophylactic treatment of patients with moderate to severe hemophilia A, without Factor VIII inhibitors

CONITEC



Population:
Children
Up to 12 years old
02 August 2023

Australia



Enoxaparin sodium

Population:
Other
High- and moderate-risk patients for thromboembolism

07 August 2023

Prophylactic use against thromboembolism

TGA B01AB05



Pharmacological Technologies



Blood

Germany



Etranacogen
dezaparvovec

Treatment of treatment
of severe and moderate
Haemophilia B

IQWiG G23-10



Germany



Luspatercept

Population:
Adult
Adults with
transfusion-
dependent beta-
thalassaemia
15 August 2023

Treatment of
transfusion-dependent
beta-thalassaemia

IQWiG A23-43



Pharmacological Technologies



Cancer


France



177Lu


Population:
Adult

10 August 2023



Treatment of metastatic, castration-resistant prostate cancer

HAS AP222



APPROVED

Early access


Australia



Glofitamab

Population:
Adult

23 August 2023



Treatment of relapsed or refractory diffuse large B-cell lymphoma

TGA



APPROVED

Provisional approval


Germany



Cemiplimab


Population:
Adult

01 August 2023




Treatment of lung cancer

IQWiG A23-37



NOT APPROVED


France



Trastuzumab deruxtecan


Population:
Adult

28 August 2023



Treatment of stomach cancer

HAS AP226



APPROVED

Early access - Renewed

Pharmacological Technologies



Cancer

Germany



Cemiplimab

Population:
Adult

01 August 2023

Treatment of cervical cancer

IQWiG A23-36

NOT APPROVED

Germany



Sotorasib

Population:
Adult
Adults with NSCLC

03 August 2023

Treatment of lung cancer

IQWiG A23-53

NOT APPROVED

Addendum to IQWiG A23-06 - no change compared to previous version

Germany



Durvalumab

Population:
Adult
Adults with hepatocellular carcinoma


11 August 2023

Treatment of hepatocellular carcinoma

IQWiG A23-27

NOT APPROVED

Germany



Tremelimumab

Population:
Adult
Adults with hepatocellular carcinoma

11 August 2023

Treatment of hepatocellular carcinoma

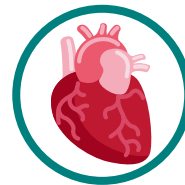
IQWiG A23-30

NOT APPROVED

Pharmacological Technologies



Cancer



Cardiovascular

Germany



Loncastuximab
tesirine

Treatment of relapsed
or refractory diffuse
large B-cell lymphoma
and high-grade B-cell
lymphoma

IQWiG A23-45



Population:
Adult

15 August 2023

Scotland



Dapagliflozin

Treatment of
symptomatic chronic
heart failure

SMC2577



Population:
Adult

07 August 2023

Germany



Luspatercept

Treatment of
myelodysplastic
syndrome

IQWiG A23-44



Population:
Adult

15 August 2023

Scotland



Icosapent ethyl

Risk reduction of
cardiovascular events

Population:
Adult
Statin-treated
patients at high
cardiovascular risk
with elevated
triglycerides (≥ 1.7
mmol/L)
07 August 2023

SMC2602



Approved with restricted
use

Pharmacological Technologies



Eye

Scotland



Aflibercept

Treatment of
retinopathy of
prematurity

SMC2612



No submission

07 August 2023

France



Ravulizumab

Treatment of
Neuromyelitis Optica
Spectrum Disorder

HAS AP236



Population:
Adult

03 August 2023

Brazil



Intravitreal
dexamethasone
implant

Treatment of diabetic
macular oedema

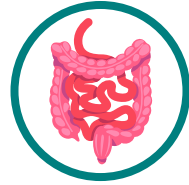
CONITEC



Population:
Unknown

02 August 2023

Pharmacological Technologies



Gastrointestinal

Wales



Mirikizumab

Population:
Adult

08 August 2023

Treatment of active
ulcerative colitis

AWTTC 4049



Excluded due to NICE
appraisal (ID3973)

Germany



Upadacitinib

Population:
Adult

01 August 2023

Treatment of Crohn's
disease

IQWiG A23-38



Pharmacological Technologies



Genitourinary

Germany



Finerenone

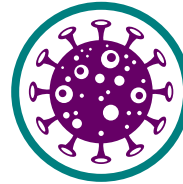
Population:
Adult
Chronic kidney disease (stage 1 and 2 with albuminuria) associated with T2DM
17 August 2023

Treatment of stage 1 and 2 chronic kidney disease

IQWiG A23-69



Addendum of IQWiG A23-14 - status not changed



Infection

Germany



Tixagevimab/
cilgavimab

Population:
Other
Adults and adolescents 12 years or older, body weight ≥ 40 kg
15 August 2023

Treatment of COVID-19

IQWiG A23-42



Germany



Finerenone

Population:
Adult
Chronic kidney disease (stage 3 and 4 with albuminuria) associated with T2DM
17 August 2023

Treatment of stage 3 and 4 chronic kidney disease

IQWiG A23-70



Addendum of IQWiG A23-15 - status not changed

Pharmacological Technologies



Metabolic/Genetic

France




Combination of
cipaglicosidase alfa
and miglustat

Population:
Adult
Late-onset
Pompe disease

03 August 2023

Treatment of late-onset
Pompe disease

HAS AP228&229



France




Setmelanotide

Population:
Other
Adults and
children aged 6
years and older

03 August 2023

Treatment of obesity
and control of hunger

HAS AP231



Early access

England




Combination of
cipaglicosidase alfa
and miglustat

Population:
Adult
Late-onset
Pompe disease

15 August 2023

Treatment of late-onset
Pompe disease

NICE TA912



Under commercial
arrangement

Germany




Setmelanotide

Population:
Adult

15 August 2023

Treatment of Bardet
Biedl syndrome

IQWiG G23-12



Pharmacological Technologies



Metabolic/Genetic



Neurology

Wales



Pegunigalsidase alfa

Population:
Adult

08 August 2023

Enzyme replacement
therapy for Fabry
disease

AWTTC 3683



Excluded due to NICE
appraisal (ID3904)

Australia



Rimegepant (as
sulfate)

Population:
Adult

08 August 2023

Treatment and
prophylaxis of migraine

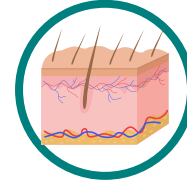
TGA N02CD06



Pharmacological Technologies



Respiratory



Skin

Brazil



Elexacaftor/
tezacaftor/ ivacaftor

Population:
Other
Patients 6 years
or older

03 August 2023

Treatment of cystic fibrosis in patients who have at least one F508del mutation in the CFTR gene

CONITEC



Scotland



Baricitinib

Population:
Adult

07 August 2023

Treatment of severe alopecia areata

SMC2572



The company did not present a sufficiently robust economic analysis

Scotland



Tezepelumab

Population:
Other
Children and
adolescents

07 August 2023

Add-on maintenance treatment of inadequately controlled severe asthma

SMC2541




Approved with restricted use

Pharmacological Technologies

Other

Scotland




Dermatophagoides pteronyssinus and Dermatophagoides farina

Population:
Other
Patients ≥ 12 years old, body weight ≥ 40 kg
07 August 2023



Treatment of of house dust mite sensitisation

SMC2613




No submission

Scotland



Selumetinib

Population:
Children
Children aged 3 years and above
07 August 2023



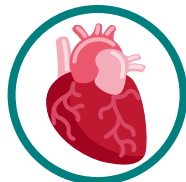
Treatment of symptomatic, inoperable plexiform neurofibromas

SMC2540



The company did not present a sufficiently robust economic analysis

Non-pharmacological Technologies



Cardiovascular



Mental health

England



Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium

Population:
Unknown

09 August 2023

Treatment of aortic valve disease

NICE IPG769



Approved for research use only

South Korea



Cognitive Behaviour Therapy using digital treatment devices

Population:
Adult
Age 19 to 50 years

11 August 2023

Cognitive therapy software downloaded onto a mobile device

PV-2023-5 NECA



Diagnostic Tests



Cancer



Infection

England



Guidance for colorectal cancer pathway referral



Quantitative faecal immunochemical testing

Population:
Adult

NICE DG56



24 August 2023

England



Variant detection to guide antibiotic use and prevent hearing loss



Genedrive MT-RNR1 ID Kit

Population:
Children
Newborns considered for treatment with aminoglycosides
10 August 2023

NICE HTE6



Early value assessment

Other Guidance



Cancer

Austria



Crisantaspase

Treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL)

AIHTA 138



Population:
Other

Adult and paediatric patients 1 month and older
21 August 2023

Austria



Elacestrant

Monotherapy for the treatment of oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer

AIHTA 140



Population:
Adult

Postmenopausal women, and men

21 August 2023

Austria



**Cedazuridine/
decitabine**

Treatment of newly diagnosed acute myeloid leukaemia (AML)

AIHTA 139



Population:
Adult

Ineligible for standard induction chemotherapy

21 August 2023

Austria



Talquetamab

Treatment of patients with relapsed and refractory multiple myeloma (MM)

AIHTA 141



Population:
Adult

≥3 prior therapies, disease progression on the last therapy
21 August 2023

Other Guidance



Cancer

Austria



Epcoritamab

Monotherapy for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

AIHTA 142



Population:
Adult

21 August 2023

Austria



Pembrolizumab

Locally advanced unresectable/ metastatic HER2+ gastric/gastro-oesophageal junction adenocarcinoma, (first-line, with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy)

AIHTA 145



Population:
Adult

21 August 2023

Austria



Nivolumab

Monotherapy for the adjuvant treatment of Stage IIB or IIC melanoma, or melanoma with involvement of lymph nodes or metastatic disease

AIHTA 144



Population:
Other
Adult and adolescents 12 years and over
21 August 2023

Austria



Tislelizumab

Monotherapy for the treatment of unresectable, locally advanced, or metastatic oesophageal squamous cell carcinoma (OSCC)

AIHTA 143



Population:
Adult

21 August 2023

Other Guidance



Cancer


Canada



PSMA-targeted
radio-
pharmaceuticals

Population:
Unknown

30 August 2023



Guidance for PSMA-PET
implementation

CADTH HC0060-000



United States



Radiotherapy

Population:
Adult

29 August 2023



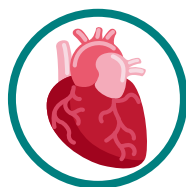
Treatment of cancers

AHRQ



Similar overall pain
response for single and
multiple fraction external
beam RT

Other Guidance



Cardiovascular

Germany



Dapagliflozin

Population:
Adult

Adults with symptomatic chronic heart failure with LVEF >40%

17 August 2023

Treatment of heart failure

IQWiG A23-71



Approved: non-T2DM non-CKD. Not approved: T2DM non-CKD

Switzerland



Surgical procedures

Population:
Adult

15 August 2023

Surgical interventions to improve blood flow to the heart vessels

FOPH



Uncertainty in clinical and cost-effectiveness compared to optimised medical therapy

Germany



Dapagliflozin

Population:
Adult

Adults with symptomatic chronic heart failure with LVEF >40%

17 August 2023

Treatment of heart failure

IQWiG A23-11



Approved: non-T2DM non-CKD, (+/-)T2DM CKD. Not approved: T2DM and non-CKD

Canada



Transcatheter Edge-To-Edge Valve Repair

Population:
Adult

Symptomatic, moderate to severe tricuspid regurgitation
22 August 2023

Treatment of tricuspid regurgitation

CADTH RC1500-000



Other Guidance



Endocrine

Canada



Somatotropin

Population:
Other
Children and
Adults with
Growth Hormone
Deficiency
04 August 2023

Treatment of growth
hormone deficiency

CADTH RC1492-000



Other Guidance



Infection

Norway



Meningococcal
ACWY vaccine

Population:
Children
Age 15 to 18 years

11 August 2023

Protection against
meningococcal disease

NIPH



Cost-effective if 50%
discount in vaccine price
and 90% vaccination
coverage

Ireland



Standard
quadrivalent
influenza
vaccination

Population:
Adult
Age 50 to 64 years,
not increased risk
of severe disease
from influenza)
18 August 2023

Vaccine providing
protection against
seasonal influenza

HIQA



Uncertainty in cost-
effectiveness

Canada



RSVpreF vaccine

Population:
Other
Infants, pregnant
women

08 August 2023

Prevention of RSV in
infants

CADTH HE0044-000



Other Guidance



Metabolic/Genetic



Neurology

Canada



Lipid panel screening

Population:
Adult
Conditions including coronary artery disease, hypertension and T1DM, T2DM
10 August 2023

Lipid panel screening for individuals with chronic conditions

CADTH RC1497-000



Norway



Transcutaneous non-invasive vagus nerve stimulation

Population:
Unknown

09 August 2023

Vagus nerve electrical stimulation

NIPH



May be cost-effective compared to standard of care alone if use is free for 93 days

Canada



Somatotropin

Population:
Children
Children with Turner Syndrome

04 August 2023

Treatment of Turner Syndrome

CADTH RC1493-000



Other Guidance



Surgery

Norway



Triclosan-coated
sutures

Population:
Unknown

29 August 2023

Prevention of wound
infection

NIPH



Uncertainty in clinical and
cost-effectiveness
compared to normal
sutures.

Other Guidance


Other

Canada



At-Home polysomnography

Population:
Adult
Adults suspected of having sleep disorders
04 August 2023



Diagnosis of sleep disorders

CADTH RC1495-000




EVIDENCE REVIEW

Canada



Opioid agonists

Population:
Unknown
15 August 2023




Use of opioid agonist therapies

CADTH HC0064-000



EVIDENCE REVIEW

United States



Cannabis and other plant-based treatments

Population:
Unknown
31 August 2023



Treatment for chronic pain

AHRQ



EVIDENCE REVIEW

Small-to-moderate improvements in pain, moderate-to-large increase in AEs

Spain




Personalised precision medicine

Population:
Unknown
August 2023



Strategies for implementing personalized precision medicine in international public health systems

AETSA



EVIDENCE REVIEW

Countries with developed PPM adoption have implemented, ongoing or planned PPM features

About Us

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Systematic Literature Reviews
Global Value Dossiers
Narrative Reviews
Rapid Reviews
Targeted Reviews

HEALTH ECONOMICS

Return on Investment
Network Meta-Analysis
Budgetary Impact Analysis
Cost-effectiveness Analysis

ACTUARIAL

Risk Management
Pricing & Reserving

MODELLING

Mortality and Morbidity Modelling
Synthetic Sample Generation
Infectious Disease Modelling

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www.heoro.com

www.evidencemapper.co.uk