

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

These decisions are categorised into one of four groups.

- Decisions of HTA bodies are categorised according to the type of intervention into Pharmacological, Non-Pharmacological and Diagnostic.
- Statements from HTA bodies in the form of guidelines on the management of a disease using specific interventions are included under Other Guidance.

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:



The reporting document states that the technology has been approved.



The reporting document states that the technology has not been approved.



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



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



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



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



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

Pharmacological Technologies



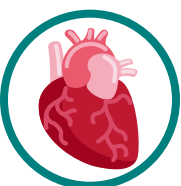
Blood

- Danicopan - France
- Heparin sodium - Australia
- Momelotinib - France
- Nonacog beta pegol - Germany



Cancer

- Amivantamab - Scotland
- Axicabtagen-Ciloleucel - Germany
- Brexucabtagene autoleucel - France
- Cemiplimab - Scotland
- Degarelix - Scotland
- Enfortumab vedotin - France
- Ivosidenib - France
- Nivolumab - Scotland
- Olaparib - Wales
- Pembrolizumab - England
- Pembrolizumab - France
- Pembrolizumab - Brazil
- Talazoparib - France
- Talquetamab - Germany
- Teclistamab - Germany
- Tisagenlecleucel - Germany
- Tisagenlecleucel - Germany
- Trastuzumab deruxtecan - Scotland



Cardiovascular

- Sacubitril/Valsartan - Germany



Endocrine

- Lonapegsomatropin - Germany
- Osilidrostat - Scotland

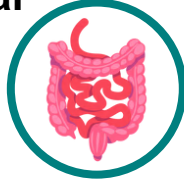
- Cyclosporin - France

Eye



Gastrointestinal

- Dupilumab - England
- Ustekinumab - Brazil



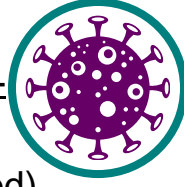
Genitourinary

- Empagliflozin - England
- Targeted-release budesonide - England



Infection

- 20-hydroxyecdysone Biophytis - France
- Dengue 1, 2, 3 and 4 (attenuated) vaccine - Brazil
- Fostensavir trometamol - Brazil
- Nirsevimab - Australia



Mental health

- Valproate - England



Genetic/Metabolic

- Beta-agalsidase - Brazil
- Cipaglicosidase alfa - Scotland
- Eladocagene exuparvovec - France
- Givosiran - Australia
- Lumasiran - Scotland
- Velmanase alfa - England
- Vosoritide - Germany
- Vutrisiran - France



Pharmacological Technologies



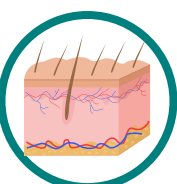
Musculoskeletal

- [Bimekizumab - Scotland](#)
- [Ixekizumab - Brazil](#)
- [Palovarotene - Australia](#)



Neurology

- [Atogepant - Australia](#)
- [Ravulizumab - England](#)
- [Ravulizumab - England](#)
- [Ravulizumab - Wales](#)
- [Risdiplam - England](#)
- [Risdiplam - Germany](#)
- [Rivastigmine - Brazil](#)



Skin

- [Bimekizumab - Germany](#)
- [Deucravacitinib - Scotland](#)
- [Oral isotretinoin - England](#)
- [Secukinumab - England](#)
- [Spesolimab - Australia](#)

Non-pharmacological Technologies



Cancer

- Endoscopic ultrasound guided radiofrequency ablation - South Korea



Endocrine

- Hybrid closed loop system – England



Eye

- Descemet's membrane peeling technique - South Korea



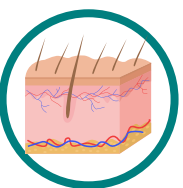
Gastrointestinal

- Gingival soft tissue augmentation - South Korea



Mental health

- Digitally enabled therapies - England
- Digitally enabled therapies - England



Skin

- Topical oxygen wound therapy - South Korea



Surgery

- Middle meningeal artery embolisation - England

Diagnostic Technologies



Cancer

- Endobronchial ultrasound - Brazil
- Molecular testing - Brazil
- Near-infrared indocyanine green lymphography with radical gastrectomy and lymphadenectomy - South Korea
- Screening for precursor lesions - Spain



Genetic/Metabolic

- Common apoE gene polymorphisms - Spain



Musculoskeletal

- HLA-B27 detection test - Brazil



Respiratory

- Artificial intelligence - South Korea

Other Guidance



Cancer

- [Loncastuximab tesirine - Germany](#)



Endocrine

- [Economic evaluation - Spain](#)



Infection

- [COVID-19 Living Review - Canada](#)



Mental health

- [Early intervention programs - Canada](#)
- [Screening tools for early detection of mood disorders](#)

Other

- [ChatGPT in radiology - Canada](#)
- [Healthcare algorithms - United States](#)



Pregnancy

- [Maternal Morbidity and Mortality - United States](#)

Pharmacological Technologies



Blood


France



Danicopan

Population:
Adult

20 December 2023



For adults with paroxysmal nocturnal hemoglobinuria (PNH) anaemia, after ravulizumab or eculizumab.

HAS AP258



Australia



Heparin sodium

Population:
Adult

07 December 2023




For treatment of deep vein thrombosis.

TGA




France



Momelotinib

Population:
Adult

11 December 2023



For splenomegaly or symptomatic anaemia in myelofibrosis, polycythaemia vera or essential thrombocythaemia, after other Janus kinase (JAK) inhibitors.

HAS AP270




Germany



Nonacog beta pegol

Population:
Children
Patients aged less than 12 years

01 December 2023



For haemophilia B.

IQWiG A23-90



Pharmacological Technologies



Cancer

Scotland



Amivantamab

For locally advanced or metastatic non-small cell lung cancer.

SMC 2638

Population:
Adult



11 December 2023

Germany



Axicabtagen-
Ciloleucel

For diffuse large B-cell lymphoma, second line.

IQWiG A23-66

Population:
Adult



21 December 2023

France



Brexucabtagene
autoleucel

For refractory/relapsed B lineage acute lymphoblastic leukemia (ALL).

HAS AP284

Population:
Adult
Adult patients aged
26 years and older



26 December 2023

Renewed post-marketing
authorisation

Scotland



Cemiplimab

For monotherapy in metastatic or locally advanced cutaneous squamous cell carcinoma.

SMC 2584

Population:
Adult




11 December 2023

Pharmacological Technologies



Cancer


Scotland



Degarelix


Population:
Unknown

11 December 2023




For prostate cancer.

SMC 2625

 **APPROVED**


France



Enfortumab vedotin


Population:
Adult

06 December 2023




Monotherapy for locally advanced or metastatic urothelial carcinoma, after platinum and anti PD-1/PD-L1 therapy.

HAS AP274

 **APPROVED**

Renewed early access

France



Ivosidenib

Population:
Adult

20 December 2023




Monotherapy for unresectable or metastatic refractory advanced cholangiocarcinoma with IDH1 R132 mutation.

HAS AP278

 **APPROVED**

Renewed early access


Scotland



Nivolumab


Population:
Adult

11 December 2023



For neoadjuvant treatment of resectable non-small cell lung cancer with platinum chemotherapy.

SMC 2619

 **APPROVED**

Pharmacological Technologies



Cancer

Wales



Olaparib

For untreated hormone-related metastatic prostate cancer with abiraterone.

AWTTC 4514



Excluded due to NICE appraisal ID3920

Population:
Unknown

08 December 2023

England



Pembrolizumab

Population:
Adult
Adults whose tumours express PD-L1 with a combined positive score of at least 1.

13 December 2023



Under commercial arrangement.

For persistent, recurrent or metastatic cervical cancer, with chemotherapy.

NICE TA939

France



Pembrolizumab

For adjuvant monotherapy in clear cell renal cell carcinoma, at increased risk of recurrence or post-nephrectomy and metastatectomy.

HAS AP279



Population:
Adult

11 December 2023

Brazil



Pembrolizumab

Population:
Unknown

06 December 2023

For metastatic colon or rectal cancer.

CONITEC



Pharmacological Technologies



Cancer

France



Talazoparib

For metastatic castration-resistant prostate cancer (mCRPC), with enzalutamide.

HAS AP272



Population:
Adult

11 December 2023

Germany



Talquetamab

For multiple myeloma.

IQWiG G23-24



Population:
Unknown

15 December 2023

Orphan drug status

Germany



Teclistamab

For multiple myeloma.

IQWiG A23-91



Population:
Adult
Adults with relapsed and refractory multiple myeloma who have previously received at least 3 therapies.

01 December 2023

Germany



Tisagenlecleucel

For diffuse large B-cell lymphoma.

IQWiG G23-21



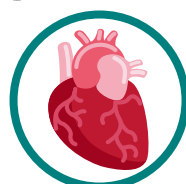
Population:
Unknown

01 December 2023

Pharmacological Technologies



Cancer



Cardiovascular

Germany



Tisagenlecleucel

Population:
Children and
Adolescent
Children,
adolescents and
young adults up to
and including 25
years of age.
01 December 2023

For acute lymphoblastic
leukaemia.

IQWiG G23-22



Orphan drug status

Germany



Sacubitril/Valsartan

Population:
Children and
Adolescent

For heart failure.

IQWiG A23-56



07 December 2023

Scotland



Trastuzumab
deruxtecan

Population:
Adult

11 December 2023

For breast cancer.

SMC 2608



Pharmacological Technologies



Endocrine



Eye

Germany



Lonapegsomatropin

Population:
Children and
Adolescent
Children and
adolescents aged 3
to 18 years

15 December 2023

For growth hormone
deficiency.

IQWiG G23-23



Orphan drug status

France



Cyclosporin

Population:
Unknown

20 December 2023

Prevention of rejection
of transfixing corneal
graft in high risk
patients with
corticosteroids.

HAS AP266



Scotland



Osilidrostat

Population:
Adult

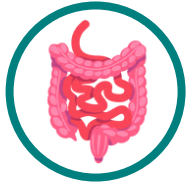
11 December 2023

For Cushing's
syndrome.

SMC 2640



Pharmacological Technologies



Gastrointestinal



Genitourinary

England



Dupilumab

For eosinophilic oesophagitis.

NICE TA938



No evidence submission

07 December 2023

Population:
Adult and Adolescent
Patients over 12
years old

England



Empagliflozin

For chronic kidney disease.

NICE TA942



Population:
Adult

20 December 2023

Population:
Adult

Brazil



Ustekinumab

For moderate-severely active Crohn's disease.

CONITEC



06 December 2023

Population:
Unknown

England



Targeted-release budesonide

For primary IgA nephropathy.

NICE TA937



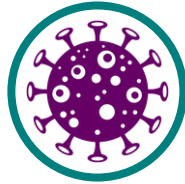
Population:
Adult

20 December 2023

Population:
Adult

Under commercial arrangement

Pharmacological Technologies



Infection


France



20-hydroxyecdysone
Biophytis


Population:
Adult

18 December 2023



For hospitalized high-risk adults with severe COVID-19.

HAS CTAP239

 NOT APPROVED


Brazil



Dengue 1, 2, 3 and 4 (attenuated) vaccine


Population:
Unknown

20 December 2023



To prevent dengue fever.

CONITEC

 APPROVED


Brazil



Fostensavir trometamol

Population:
Adult

06 December 2023



For multidrug-resistant HIV.

CONITEC

 NOTE FROM REPORT

Recommended for public consultation with a favorable opinion


Australia



Nirsevimab


Population:
Children
Children up to 24 months of age

08 December 2023



For prevention of respiratory syncytial virus (RSV) infection.

TGA

 APPROVED

Pharmacological Technologies



Mental Health



Genetic/Metabolic

England



Valproate

For bipolar disorder.

NICE CG185



Population:
Adult, Adolescent
and Children

21 December 2023

Brazil



Beta-agalsidase

For classical Fabry
disease.

Population:
Adult, Adolescent
and Children
Patients aged 8 or
older

CONITEC



07 December 2023

Scotland



Cipaglucosidase alfa

For long-term enzyme
replacement therapy
with miglustat for
Pompe disease.

Population:
Adult

SMC 2606



11 December 2023

Pharmacological Technologies



Genetic/Metabolic

France



Eladocagene
exuparovec

Population:
Adult, Adolescent
and Children
Patients 18 months
of age and older

21 December 2023

For severe aromatic L-
amino acid
decarboxylase (AADC)
deficiency.

HAS AP277



Renewed early access

Australia



Givosiran

Population:
Adult and
Adolescent
Adults and
adolescents aged 12
years and older

15 December 2023

For acute hepatic
porphyria.

TGA



Scotland



Lumasiran

Population:
Adult, Adolescent
and Children

11 December 2023

For primary
hyperoxaluria type 1.

SMC 2639



England



Velmanase alfa

Population:
Adult, Adolescent
and Children

13 December 2023

For alpha-
mannosidosis.

NICE HST29

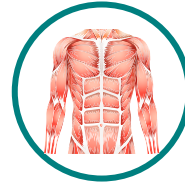


Under commercial
arrangement.

Pharmacological Technologies



Genetic/Metabolic



Musculoskeletal

Germany



Vosoritide

For achondroplasia.

IQWiG A23-92



Population:
Adult, Adolescent
and Children
Patients aged 2 and
over

01 December 2023

Scotland



Bimekizumab

For axial
spondyloarthritis.

SMC 2616



Population:
Adult

11 December 2023

France



Vutrisiran

For hereditary
transthyretin (hATTR)
amyloidosis in stage 1/2
polyneuropathy.

HAS CTAP276



Population:
Adult

20 December 2023

Renewed early access

Brazil



Ixekizumab

For axial
spondyloarthritis.

CONITEC

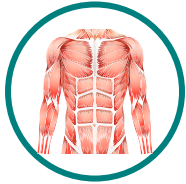


Population:
Adult

06 December 2023

Postponed until next
meeting

Pharmacological Technologies



Musculoskeletal



Neurology

Australia



Palovarotene

For heterotopic ossification in fibrodysplasia ossificans progressiva.

TGA



Population:
Adult, Adolescent
and Children
Adults and children
aged 8 years and
above

11 December 2023

Australia



Atogepant

For migraine.

TGA



Population:
Adult
Adults who have at
least 4 migraine days
per month

20 December 2023

England



Ravulizumab

For AQP4 antibody-positive neuromyelitis optica spectrum disorder.

NICE TA941



Population:
Adult

20 December 2023

Submission withdrawn

Pharmacological Technologies



Neurology

England



Ravulizumab

Population:
Adult

20 December 2023

For generalised
myasthenia gravis.

NICE TA940



Submission withdrawn

Wales



Ravulizumab

Population:
Adult

19 December 2023

For neuromyelitis optica
spectrum disorder.

AWTTC 5138



Excluded due to NICE
appraisal TA941

England



Risdiplam

Population:
Adult, Adolescent
and Children
People with 5q spinal
muscular atrophy of
all ages

15 December 2023

For spinal muscular
atrophy.

NICE TA755



Under commercial
arrangement, for all ages.

Germany



Risdiplam

Population:
Children
Patients less than 2
months of age

15 December 2023

For spinal muscular
atrophy.

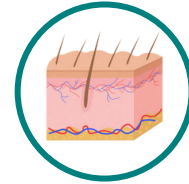
IQWiG A23-93



Pharmacological Technologies



Neurology



Skin

Brazil



Rivastigmine

For Parkinson's disease.

CONITEC



Postponed until next meeting

Population:
Unknown

06 December 2023

Germany



Bimekizumab

For psoriatic arthritis.

IQWiG A23-60



Population:
Adult

21 December 2023

Scotland



Deucravacitinib

For plaque psoriasis.

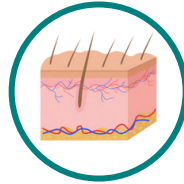
SMC 2581



Population:
Adult

11 December 2023

Pharmacological Technologies



Skin

England



Oral isotretinoin

For acne vulgaris.

NICE NG198



Population:
Adult and
Adolescent
Adults and children
over 12

07 December 2023

England



Secukinumab

For moderate to severe
hidradenitis
suppurativa.

NICE TA935



Population:
Adult

06 December 2023

Under commercial
arrangement.

Australia



Spesolimab

For generalised pustular
psoriasis.

TGA



Population:
Adult
Adult patients with
generalised pustular
psoriasis.

08 December 2023

Non-pharmacological Technologies



Cancer



Endocrine

South Korea



Endoscopic
ultrasound guided
radiofrequency
ablation

Population:
Unknown

07 December 2023

For pancreatic tumours.

NECA



Further research needed

England



Hybrid closed loop
system

Population:
Adult and Children

19 December 2023

For managing blood
glucose levels in type 1
diabetes.

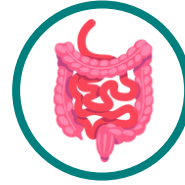
NICE TA943



Non-pharmacological Technologies



Eye



Gastrointestinal

South Korea



For Fuchs corneal endothelial dystrophy.



Descemet's membrane peeling technique

NECA

Population:
Unknown



Further evidence required

07 December 2023

South Korea



For loss of attached gingiva and gingival recession.



Gingival soft tissue augmentation

NECA

Population:
Unknown

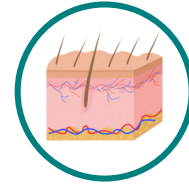


07 December 2023

Non-pharmacological Technologies



Mental Health



Skin

England



South Korea



For anxiety disorders.



For skin ulcers due to diabetes, venous stasis, post-operative infections and gangrenous lesions, bedsores, cut/infected traumatic wounds, skin grafts, and burns.

Digitally enabled therapies

NICE HTE9

Topical oxygen wound therapy

NECA

Population:
Adult



Population:
Unknown



14 December 2023

NICE has developed tools and resources to help organisations put this guidance into practice.

07 December 2023

England



For depression.

Digitally enabled therapies

NICE HTE8

Population:
Adult



14 December 2023

NICE has developed tools and resources to help organisations put this guidance into practice.

Non-pharmacological Technologies



Surgery

England



Middle meningeal
artery embolisation

Population:
Unknown

14 December 2023

For chronic subdural
haematomas.

NICE IPG779



Approved for research
use only

Diagnostic Technologies



Cancer

Brazil



Endobronchial
ultrasound

Assessment of patients
with lung cancer.

CONITEC

Population:
Unknown



Recommended for public
consultation with a
favorable opinion

08 December 2023

Brazil



Molecular testing

For HPV detection and
cervical cancer
screening.

CONITEC

Population:
Unknown



Recommended for public
consultation with a
favorable opinion

08 December 2023

South Korea



Near-infrared
indocyanine green
lymphography with
radical gastrectomy
and
lymphadenectomy

For stomach cancer.

NECA

Population:
Unknown



07 December 2023

Spain



Screening for
precursor lesions

Population:
Adult

People at high risk of
developing anal cancer,
specifically (HIV-
positive) men who have
sex with men (MSM)

December 2023

For the detection of anal
cancer.

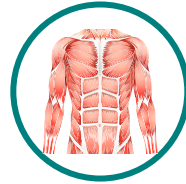
AQuAS



Diagnostic Technologies



Genetic/Metabolic



Musculoskeletal

Spain



Common apoE gene polymorphisms

For associations between familial dysbetalipoproteinaemia and late-onset Alzheimer's disease.

AQuAS



Population:
Adult
Adults and older adults

22 December 2023

Brazil



HLA-B27 detection test

Population:
Unknown

08 December 2023

For suspected axial spondyloarthritis.

CONITEC



Recommended for public consultation with a favorable opinion

Diagnostic Technologies




Respiratory

South Korea



Artificial intelligence

Population:
Adult and
Adolescent
Patients aged 14 and
over who underwent
X-ray
12 December 2023



For detection of
abnormalities in chest
radiography images.

NECA



Further evidence required

Other Guidance



Cancer



Endocrine

Germany



Loncastuximab
tesirine

For relapsed or refractory diffuse large B cell lymphoma (DLBCL) and high grade B cell lymphoma (HGBL).

IQWiG G23-25



Population:
Adult

01 December 2023

Spain



Economic evaluation

To assess the future burden of excess cases of diabetes mellitus type 1 during the COVID pandemic.

AQuAS



Population:
Adult, Adolescent
and Children

01 December 2023

Other Guidance



Infection



Mental Health

Canada



COVID-19 Living Review

Post-COVID-19 Condition Treatment and Management.

CADTH RE0040-000/RE0040-004



Population: Unknown

12 December 2023

Canada



Early intervention programs

Population: Adult and Adolescent

18 December 2023

For eating disorders.

CADTH HT0040-000 - OP0552-000



Spain



Screening tools for early detection of mood disorders

Population: Adult

21 December 2023

For the assessment and management of mood disorders.

AQuAS



Other Guidance

Other



Pregnancy

Canada



ChatGPT in radiology

Appropriate imaging and workflow efficiencies.

CADTH



Population:
Unknown

21 December 2023

United States



Maternal Morbidity and Mortality

To assess social and structural determinants of maternal morbidity and mortality.

AHRQ



Population:
Adult
Pregnant women

21 December 2023

United States



Healthcare algorithms

To assess the impact of racial and ethnic disparities in health and healthcare

AHRQ



Population:
Unknown
Black patients

08 December 2023

About Us

Crystallise provides an innovative approach to identify and synthesise information, using AI to automate processes and assist our experts to produce deliverables that provide real value to clients.

Our team of researchers, medical writers and copy-editors deliver strategically-relevant and comprehensive written reports as well as visually informative summary slide decks, to suit internal business development, market access, journal publication and health technology assessment submissions.

REVIEWS

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