

This newsletter summarises final decisions from HTA bodies around the world from September 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

- Concizumab - Australia
- Luspatercept - Germany



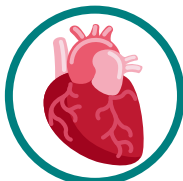
Cancer

- Bevacizumab - Australia
- Carfilzomib - Brazil
- Crizotinib - Scotland
- Darolutamide - Germany
- Daratumumab - Scotland
- Daratumumab + bortezomib - Brazil
- Glofitamab - Wales
- Ibrutinib - Scotland
- Ivosidenib - Australia
- Lisocabtagene maraleucel - France
- Lisocabtagene maraleucel - France
- Mosunetuzumab - Scotland
- Nivolumab - France
- Nivolumab + ipilimumab - Scotland
- Pembrolizumab - England
- Ponatinib - Brazil
- Teclistamab - France



Eye

- Ravulizumab - Germany



Cardiovascular

- Mavacamten - France
- Mavacamten - England
- Sacubitril/valsartan - Germany

- Olipudase alfa - Australia
- Semaglutide - England
- Setmelanotide - France
- Vutrisiran - Scotland
- Patisiran sodium - Brazil

- Glecaprevir-pibrentasvir - Canada
- Pretomanid - Brazil

- Esketamine - Germany

- Vamorolone - France

- Rimegepant - Scotland

- Birch bark extract (Filsuvez) - England

- Secukinumab - Germany

- Somatotropin - Canada



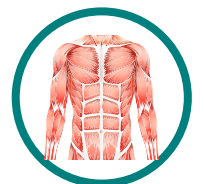
Genetic/
Metabolic



Infection



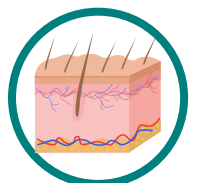
Mental health



Musculoskeletal



Neurology



Skin

Other

Non-pharmacological Technologies



Cancer

- [AI technologies for planning radiotherapy treatment - England](#)
- [Optune - Canada](#)
- [Cryotherapy - England](#)
- Other



Genetic/
Metabolic

- [Glucose monitoring - Ireland](#)



Genitourinary

- [Transurethral water-jet ablation - England](#)



Infection

- [Vibrio cholerae - Australia](#)



Mental health

- [KardiaMobile 6L - England](#)



Pregnancy

- [Removal, preservation and reimplantation of ovarian tissue - England](#)

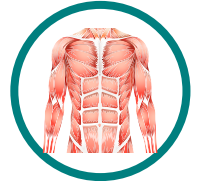
Other Guidance



Blood

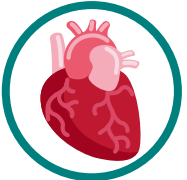
- [RBC aggregating force - South Korea](#)

- [Anti-ENA antibody - South Korea](#)



Musculoskeletal

- [Internal spine fixation - South Korea](#)
- [Intra-articular glucocorticoid injections - Switzerland](#)
- [Platelet Rich Plasma Injections - South Korea](#)



Cardiovascular

- [Wireless pacemakers - Spain](#)



Cancer

- [AI for X-ray analysis - England](#)
- [Lisocabtagen maraleucel - Germany](#)
- [Shape-guided robot-assisted bronchoscopy - South Korea](#)

- [Patient Specific 3D-Printed Model - South Korea](#)
- [Pectoralis nerve block - South Korea](#)
- [Surgery simulation - South Korea](#)



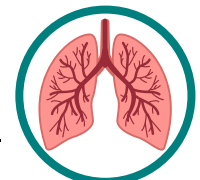
Surgery



Genetic/
Metabolic

- [Eladocagene exuparvovec - Scotland](#)
- [Olipudase alfa - Scotland](#)

- [Autologous bone marrow stem cell treatment - South Korea](#)



Respiratory



Mental health

- [Pharmacologic and Nonpharmacologic Treatments - United States](#)

- [Cannabis and other plant-based treatments - United States](#)

Other



Neurology

- [CGRP antagonists - Switzerland](#)

- [Vital pulpotomy - South Korea](#)

Pharmacological Technologies



Blood

Australia



Concizumab

For treatment of haemophilia A (congenital factor VIII [FVIII] deficiency) with FVIII inhibitor.

TGA



Population:
Adult and Adolescent
Over 12 years old.
29 September 2023

Germany



Luspatercept

For the treatment of anaemia associated with non-transfusion-dependent beta-thalassaemia.

IQWiG - A23-20



Population:
Adult
21 September 2023

Hint of minor added benefit.

Pharmacological Technologies



Cancer

Australia



Bevacizumab

For cancer treatment by reducing tumour vascularisation.

TGA - LO1FG01



Population:
Unknown

18 September 2023

Brazil



Carfilzomib

For relapsed or refractory multiple myeloma.

CONITEC



Population:
Unknown
Patients who have received prior therapy.
13 September 2023

Scotland



Crizotinib

As monotherapy for relapsed/ refractory systemic ALK-positive ALCL or recurrent/ refractory ALK-positive unresectable inflammatory myofibroblastic tumour (IMT).
SMC2621



Non submission

Population:
Children
Pediatric patients (6 to 18 years)

11 September 2023

Germany



Darolutamide

For the treatment of metastatic hormone-sensitive prostate cancer.

IQWiG - A23-21



Population:
Adult

21 September 2023

Indication of major added benefit.

Pharmacological Technologies



Cancer

<p>Scotland</p>  <p>Daratumumab</p> <p>Population: Adult</p> <p>11 September 2023</p>	<p>With lenalidomide and dexamethasone for adults with newly diagnosed multiple myeloma, ineligible for autologous stem cell transplant.</p> <p><i>SMC2536</i></p> <p> APPROVED</p>	<p>Brazil</p>  <p>Daratumumab + bortezomib</p> <p>Population: Unknown</p> <p>Patients who have received prior therapy.</p> <p>13 September 2023</p>	<p>With dexamethasone for relapsed and/or refractory multiple myeloma.</p> <p><i>CONITEC</i></p> <p> NOT APPROVED</p> <p>Final recommendation of non-incorporation</p>
<p>Wales</p>  <p>Glofitamab</p> <p>Population: Adult</p> <p>07 September 2023</p>	<p>For relapsed/ refractory DLBCL, HGBCL and PMBCL after 2 or more lines of systemic treatments.</p> <p><i>AWMSG - 4832</i></p> <p> EXCLUDED</p> <p>Excluded due to NICE appraisal</p>	<p>Scotland</p>  <p>Ibrutinib</p> <p>Population: Adult</p> <p>11 September 2023</p>	<p>With venetoclax for adults with previously untreated chronic lymphocytic leukaemia.</p> <p><i>SMC2543</i></p> <p> APPROVED</p>

Pharmacological Technologies



Cancer

Australia



Ivosidenib

For treatment of newly diagnosed or relapsed/refractory acute myeloid leukaemia (AML).

TGA - L01XX62



Monotherapy or in combination in newly diagnosed; monotherapy in relapsed/refractory.

28 September 2023

Population:
Unknown

France



Lisocabtagene maraleucel

For treatment of follicular grade 3B lymphoma.

HAS - AP243



Early access authorisation.

Population:
Adult

20 September 2023

France



Lisocabtagene maraleucel

For treatment of diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma (HLBCL) or primary mediastinal large B-cell lymphoma (LMPGCB).

HAS - AP242



Renewed early access.

20 September 2023

Population:
Adult

Scotland



Mosunetuzumab

For adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systemic therapies.

SMC2542



Population:
Adult

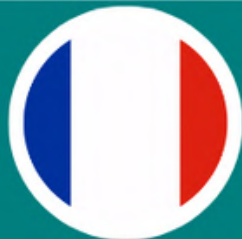
11 September 2023

Pharmacological Technologies



Cancer

France



Nivolumab

For treatment of resectable non-small cell lung cancer with PD-L1 $\geq 1\%$ threshold and no EGFR sensitising mutation or ALK translocation.

HAS - AP267

Population:
Adult



Early access authorisation
- Combined with platinum-based chemotherapy.

11 September 2023

Scotland



Nivolumab +
ipilimumab

For first-line treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with PD-L1 expression $\geq 1\%$.

SMC2620

Population:
Adult



Indication under review -
SMC not submitted for
indication

11 September 2023

England



Pembrolizumab

For treatment of endometrial, biliary, colorectal, gastric or small intestine cancer with high MSI or MRD.

NICE - TA914

Population:
Adult



Recommended if pembrolizumab is stopped at two years or according to cancer progression.

20 September 2023

Brazil



Ponatinib

For rescue treatment in chronic myeloid leukaemia.

CONITEC

Population:
Unknown
Patients in whom tyrosine kinase inhibitors have failed.
13 September 2023



Final recommendation of non-incorporation

Pharmacological Technologies



Cancer



Eye

France



Teclistamab

For treatment of relapsed/refractory multiple myeloma, with at least three previous treatments and disease progression.

HAS - AP244



Early access renewed -
Use as monotherapy.

20 September 2023

Population:
Adult

Germany



Ravulizumab

For neuromyelitis optica spectrum diseases.

IQWiG - A23-50

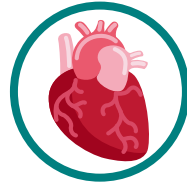


Benefit not proven

Population:
Adult

15 September 2023

Pharmacological Technologies



Cardiovascular

France



Mavacamten

For treatment of persistent obstructive hypertrophic cardiomyopathy.

HAS - AP251



Population:
Adult

28 September 2023

England



Mavacamten

For treatment of symptomatic obstructive hypertrophic cardiomyopathy.

NICE - TA913



Population:
Adult

Adults with a New York Heart Association class of 2 to 3.

06 September 2023

Use as an add-on to standard care

Germany



Sacubitril/valsartan

For children and adolescents with heart failure.

IQWiG - A23-56



Population:
Children and Adolescent

15 September 2023

Benefit not proven

Pharmacological Technologies



Genetic/Metabolic

Australia



Olipudase alfa

For treatment of acid sphingomyelinase deficiency (ASMD) or other inherited metabolic disorders.

TGA - A16AB25



Population:
Adult and Children

06 September 2023

France



Setmelanotide

For treatment of obesity and hunger control.

HAS - AP245



Population:
Adult and Children
Adults and children 6 years or older.

20 September 2023

Renewed post-market authorisation.

England



Semaglutide

For treatment of overweight and obesity.

NICE - TA875



Population:
Adult
At least one weight-related comorbidity and either BMI >35 or 30 < BMI < 34.9 but requiring referral to specialist management.

04 September 2023

Use for maximum 2 years, with specialist advice.

Scotland



Vutrisiran

For hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adults with stage 1 or stage 2 polyneuropathy.

SMC2596



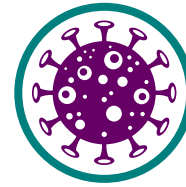
Population:
Adult

11 September 2023

Pharmacological Technologies



Metabolic/Genetic



Infection

Brazil



Patisiran sodium

For hereditary transthyretin-related amyloidosis (hATTR) with stage 2 polyneuropathy.

CONITEC



Final recommendation of non-incorporation

Population:
Unknown
Patients with inadequate response to tafamidis.
13 September 2023

Canada



Glecaprevir-pibrentasvir

For treatment of chronic hepatitis C virus infection.

CADTH - RC1502-000



Population:
Children and Adolescent

20 September 2023

Brazil



Pretomanid

For drug-resistant tuberculosis.

CONITEC



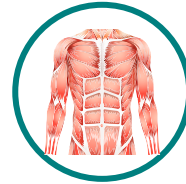
Population:
Unknown

13 September 2023

Pharmacological Technologies



Mental health



Musculoskeletal

Germany



Esketamine

Addendum to order
A23-18 for treatment-
resistant major
depressive disorder.

IQWiG - A23-75



Hint of considerable
added benefit.

21 September 2023

France



Vamorolone

For treatment of
Duchenne muscular
dystrophy (DMD).

HAS - AP201



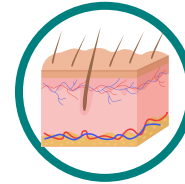
Population:
Children
Aged 4 to 7
years.

20 September 2023

Pharmacological Technologies



Neurology



Skin

Scotland



Rimegepant

For prevention of episodic migraine in adults who have ≥ 4 migraine attacks per month.

SMC2603



≥ 4 migraine attacks/month,
<15 headache days/month,
 ≥ 3 migraine preventive treatments failed.

Population:
Adult

11 September 2023

England



Birch bark extract
(Filsuvez)

For treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa.

NICE - HST28



Population:
Adult, Adolescent
and Children
 ≥ 6 months and
older.

20 September 2023

Germany



Secukinumab

For active moderate-to-severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic therapy

IQWiG - A23-51



Population:
Adult

15 September 2023

Benefit not proven

Pharmacological Technologies

Other

Canada



Somatotropin

Population:

Children

Children with short stature born small for gestational age, or with idiopathic short stature.

15 September 2023



For treatment of short stature.

CADTH - RC1501-000



Approved for small-for-gestational-age children, not approved for idiopathic short stature.

Non-pharmacological Technologies



Cancer



Genetic/Metabolic

England



To aid contouring for radiotherapy treatment-planning.

NICE - HTE11



Nine artificial intelligence (AI) technologies can be used in the NHS.

27 September 2023

AI technologies for planning radiotherapy treatment
Population: Unknown

Ireland



For type 1 diabetes mellitus.

Glucose monitoring

HIQA



Population: Adult

29 September 2023

For type 1 diabetes mellitus.

Canada



For treatment of newly diagnosed glioblastoma.

INESSS



Optune

Population: Adult

26 September 2023

For treatment of newly diagnosed glioblastoma.

Non-pharmacological Technologies



Genitourinary


England



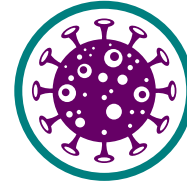
Transurethral water-jet ablation

Population:
Unknown

14 September 2023

 For treatment of lower urinary tract symptoms caused by benign prostatic hyperplasia.

NICE - IPG770




Infection

Australia



Vibrio cholerae

Population:
Adult and Children
Adults and children over two years of age.
18 September 2023

 For active immunisation against disease caused by *Vibrio cholerae*.

TGA - J07AE02



Non-pharmacological Technologies



Mental health

England



KardiaMobile 6L

Population:
Adult
Patients receiving
antipsychotic
medication, such as
schizophrenia,
psychosis, and
bipolar disorder.
26 September 2023

For measuring cardiac
QT interval in adults
taking antipsychotic
medication.
NICE - HTE10



A repeat QT interval
measurement is
recommended using a 12-
lead ECG.



Pregnancy

England



Removal,
preservation and
reimplantation of
ovarian tissue

Population:
Unknown

21 September 2023

For fertility restoration
after gonadotoxic
treatment.
NICE - IPG772



Non-pharmacological Technologies



Respiratory


England



Cryotherapy

Population:
Unknown

14 September 2023



For treatment of chronic rhinitis.

NICE - IPG771

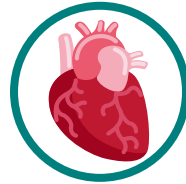


For research use only.

Other Guidance



Blood



Cardiovascular

South Korea



Use as a microfluidic scanning method.



RBC aggregating force

NECA - HTA-2023-47



Population:
Adult

27 September 2023

Spain



For bradycardia and cardiac conduction block.



Wireless pacemakers

AETSA



Population:
Adult

September 2023

Other Guidance



Cancer

England



AI for X-ray analysis

Population:
Adult
Adults with
suspected lung
cancer.
28 September 2023

For analysis of chest X-rays.

NICE - HTE12



More research is needed.

Germany



Lisocabtagen
maraleucel

Population:
Adult
Relapsed/ refractory
patients with DBCL,
highly malignant BCL,
primary mediastinal
LBCL, or grade 3B FL
01 September 2023

For treatment of lymphoma.

IQWiG - A23-48



Patients <65 years show unquantifiable added benefit. Benefits not proven in other patients.

South Korea



Shape-guided robot-assisted bronchoscopy

Population:
Unknown

27 September 2023

For surgical benefit in lung cancer patients.

NECA - HTA-2023-50



Other Guidance



Genetic/Metabolic


Scotland



Eladocagene
exuparvovec

Population:
Adult and Children
Patients aged
over 18 months

11 September 2023



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

SMC2586



Indication under review
under ultra orphan drug
assessment.


Scotland



Olipudase alfa

Population:
Adult and Children

11 September 2023



For non-CNS
manifestations of Acid
Sphingomyelinase
Deficiency (ASMD).

SMC2560



Indication under review -
assessment under ultra
orphan drug framework.

Other Guidance



Mental health


United States



Pharmacologic and
Nonpharmacologic
Treatments

Population:
Unknown

12 September 2023

 Use for the treatment of
Post-Traumatic Stress
Disorder.

AHRQ



Neurology


Switzerland



CGRP antagonists

Population:
Adult

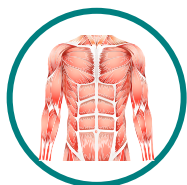
22 September 2023

 For treatment of chronic
and episodic migraine.

BAG - H0055



Other Guidance



Musculoskeletal

South Korea



Anti-ENA antibody

To diagnose idiopathic inflammatory myopathy (IIM).

NECA - HTA-2023-45

Population:
Adult and Children



06 September 2023

South Korea



Internal spine fixation

To increase spine stability and strength in osteoporosis.

NECA - HTA-2023-43

Population:
Adult
Patients with osteoporosis or osteopenia.
06 September 2023



Switzerland



Intra-articular glucocorticoid injections

Use for the management of knee or hip osteoarthritis.

BAG - H0058

Population:
Adult
Patients with primary osteoarthritis of the knee or hip.
29 September 2023



South Korea



Platelet Rich Plasma Injections

For treatment of rotator cuff tendinopathy

NECA - HTA-2023-48

Population:
Adult

27 September 2023



Other Guidance



Surgery

South Korea



Patient Specific 3D-
Printed Model

Population:
Unknown

27 September 2023



For surgical benefit in
liver transplantations.

NECA - HTA-2023-49




South Korea



Pectoralis nerve
block

Population:
Unknown

06 September 2023



For treatment of post-
operative pain after
chest surgery.

NECA - HTA-2023-44




South Korea



Surgery simulation

Population:
Unknown

06 September 2023



Training for high-
difficulty surgery.

NECA - HTA-2023-42



Other Guidance



Respiratory

South Korea



Autologous bone marrow stem cell treatment

Population:
Adult and Adolescent
Patients over 12 years of age.
06 September 2023

For treatment of severe asthma.

NECA - HTA-2023-41



United States



Cannabis and other plant-based treatments

Population:
Adult and Adolescent

20 September 2023

For treatment of chronic pain.

AHRQ



South Korea



Vital pulpotomy

Population:
Adult
Patients with irreversible pulpitis in living teeth with recognised pulp vitality.

27 September 2023

To regenerate secondary dentin and maintain pulp vitality

NECA - HTA-2023-46



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.

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Global Value Dossiers
Narrative Reviews
Rapid Reviews
Targeted Reviews

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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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Registered address

17 High Street,
Stanford-le-Hope,
Essex, SS17 0HD
+44 (0)1375 517878

Company No: 7980921

Data Protection Act Registration Number: Z3363643

Websites:

www.crystallise.com

www.heoro.com

www.evidencemapper.co.uk