

## This newsletter summarises final decisions from HTA bodies around the world from February 2024.

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

- Apadamtase alfa - France
- Epoetin alfa - Brazil
- Ferric derisomaltose - Brazil
- Hydroxyurea - Brazil
- Hydroxyurea 100 and 1000 mg - Brazil
- Midostaurin - Germany
- Ravulizumab - Brazil

### Cancer

- Bevacizumab - Australia
- Cabozantinib - Scotland
- Crisantaspase - Australia
- Elacestrant - France
- Elacestrant - Germany
- Idecabtagene vicleucel - Austria
- Idecabtagene vicleucel - France
- Lanreotide acetate and extended release octreotide acetate - Brazil
- Loncastuximab tesirine - Scotland
- Midostaurin - Germany
- Niraparib/abiraterone acetate - Germany
- Nivolumab - Germany
- Ripretinib - France
- Sacituzumab govitecan - Germany
- Selpercatinib - Austria
- Trastuzumab deruxtecan - Wales
- Trifluridine/Tipiracil - Germany

### Cardiovascular

- Lanadelumab - France
- Mavacamten - Germany

### Endocrine

- Tirzepatide - Germany

### Eye

- Brolucizumab - Germany

### Genitourinary

- Difelikefalin - Scotland

### Infection

- Nirmatrelvir/Ritonavir - Brazil

### Genetic/Metabolic

- Cipaglucoasidase alfa - Germany
- Migalastat - Germany
- Migalastat - Germany
- Somapacitan - Germany
- Vosoritide - Germany

### Musculoskeletal

- Baricitinib - Germany
- Baricitinib - Germany
- Baricitinib - Germany

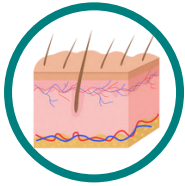


## *Pharmacological Technologies*



### **Neurology**

- Ravulizumab - Scotland
- Ravulizumab - Scotland
- Rivastigmine - Brazil



### **Skin**

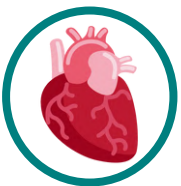
- Baricitinib - Germany
- Dupilumab - Scotland
- Secukinumab - Scotland

## Non-pharmacological Technologies



### Cancer

- Laparoscopic endoscopic cooperative surgery - South Korea
- Markerless real-time surface guided radiation therapy - South Korea
- MRI-guided transurethral ultrasound ablation - South Korea
- Radiofrequency thermal ablation - Brazil
- Radioguided surgery with I125-radioactive seeds - Spain



### Cardiovascular

- Endograft fixation - South Korea
- Radiofrequency Catheter Ablation - South Korea



### Genitourinary

- MRI-guided transurethral ultrasound ablation - South Korea



### Mental health

- Emotional freedom technique - South Korea



### Pregnancy

- Birth cohort testing - Ireland

## Diagnostic Technologies



### Cancer

- Endobronchial ultrasonography - Spain
- Molecular testing - Brazil
- RT-PCR of EGFR - Brazil



### Cardiovascular

- AI-assisted 12-lead electrocardiography - South Korea



### Pregnancy

- Screening test for HTLV 1-2 - Brazil

## Other Guidance



### Blood

- [Etranacogene dezaparvovec - Germany](#)
- [Exagamglogen Autotemcel - Germany](#)



### Cancer

- [Odronextamab - Germany](#)
- [Odronextamab - Germany](#)



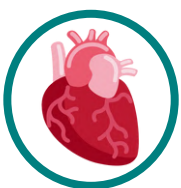
### Gastrointestinal

- [Biodegradable stents - Spain](#)
- [Clinical and instrumental swallowing assessment - Canada](#)
- [Tofacitinib and Other Drugs - Canada](#)



### Infection

- [Dalbavancin - Germany](#)
- [Respiratory syncytial virus vaccines - Canada](#)
- [Vaccine for tuberculosis - England](#)



### Cardiovascular

- [Implantable devices - Spain](#)



### Neurology

- [Exoskeleton - Spain](#)

### Other

- [National rare disease strategies - Ireland](#)
- [Selective gut decontamination - England](#)

### Pregnancy

- [Newborn screening - Canada](#)





## Pharmacological Technologies



### Blood

France



Apadamtase alfa

For congenital thrombotic thrombocytopenic purpura due to ADAMTS13 deficiency.

HAS - AP281

Population:  
Adult and Adolescent  
>12 years



16 February 2024

Brazil



Epoetin alfa

For sickle cell disease.

CONITEC

Population:  
Unknown



01 February 2024

Brazil



Ferric derisomaltose

For anaemia due to iron deficiency.

CONITEC

Population:  
Adult



Recommended with a favourable opinion

01 February 2024

Brazil



Hydroxyurea

For sickle cell disease (SS, Sbeta0 and SD Punjab).

CONITEC

Population:  
Children  
9 to 24 months old



01 February 2024

## Pharmacological Technologies



### Blood

Brazil



Hydroxyurea 100  
and 1000 mg

Population:  
Adult, Adolescent  
and Children  
≥9 months old

01 February 2024



For sickle cell disease.

CONITEC



100 mg approved, 1,000  
mg not approved


Germany



Midostaurin

Population:  
Adult

15 February 2024



For aggressive systemic  
mastocytosis  
with/without associated  
haematologic neoplasia,  
or mast cell leukaemia.

IQWiG - A23-111




Brazil



Ravulizumab

Population:  
Unknown

01 February 2024



For paroxysmal  
nocturnal  
haemoglobinuria.

CONITEC





## Pharmacological Technologies



<p>Australia</p>  <p><b>Bevacizumab</b></p> <p>Population: Unknown</p> <p>06 February 2024</p>	<p>For </p> <p>advanced/metastatic/ recurrent colorectal cancer, breast cancer, NSCLC, renal cell cancer, glioma; epithelial ovarian, fallopian tube or primary peritoneal cancer; cervical cancer.</p> <p>TGA</p> 	<p>Scotland</p>  <p><b>Cabozantinib</b></p> <p>Population: Adult</p> <p>12 February 2024</p>	<p></p> <p>Monotherapy for locally advanced or metastatic differentiated thyroid carcinoma.</p> <p>SMC 2590</p> 
<p>Australia</p>  <p><b>Crisantaspase</b></p> <p>Population: Adult and Children</p> <p>27 February 2024</p>	<p></p> <p>For acute lymphoblastic leukaemia.</p> <p>TGA</p> 	<p>France</p>  <p><b>Elacestrant</b></p> <p>Population: Adult</p> <p>14 February 2024</p>	<p></p> <p>Monotherapy for refractory locally advanced or metastatic ER+, HER2- breast cancer with ESR1 gene mutation.</p> <p>HAS - AP288</p> 

## Pharmacological Technologies



Germany



Elacestrant

Population:  
Adult

01 February 2024



For refractory ER+,  
HER2-, locally advanced  
or metastatic breast  
cancer with ESR1  
mutation.

*IQWiG - A23-104*



NOT APPROVED


Austria



Idecabtagene  
vicleucel

Population:  
Adult

12 February 2024



For relapsed/refractory  
multiple myeloma.

*AIHTA - 162*



APPROVED

EMA approved, FDA not  
approved


France



Idecabtagene  
vicleucel

Population:  
Adult

22 February 2024



For relapsed/refractory  
multiple myeloma.

*HAS - AP134*



APPROVED


Brazil



Lanreotide acetate  
and extended  
release octreotide  
acetate

Population:  
Unknown

01 February 2024



For  
gastroenteropancreatic  
endocrine tumours.

*CONITEC*



APPROVED

Lanreotide acetate  
approved, ER octreotide  
acetate not approved.

## Pharmacological Technologies



<p>Scotland</p>  <p><b>Loncastuximab tesirine</b></p> <p>Population: Adult</p> <p>12 February 2024</p>	 <p>Monotherapy for relapsed/refractory diffuse large or high-grade B-cell lymphoma.</p> <p><i>SMC 2609</i></p> <p> <b>APPROVED</b></p> <p>Restricted approval</p>	<p>Germany</p>  <p><b>Midostaurin</b></p> <p>Population: Adult</p> <p>15 February 2024</p>	 <p>Maintenance therapy for newly diagnosed acute myeloid leukaemia with FMS-TK3 mutation.</p> <p><i>IQWiG - A23-110</i></p> <p> <b>NOT APPROVED</b></p>
<p>Germany</p>  <p><b>Niraparib/ abiraterone acetate</b></p> <p>Population: Adult</p> <p>15 February 2024</p>	 <p>For metastatic castration-resistant prostate cancer (mCRPC).</p> <p><i>IQWiG - A23-107</i></p> <p> <b>APPROVED</b></p> <p>Approved for first-line only</p>	<p>Germany</p>  <p><b>Nivolumab</b></p> <p>Population: Adult</p> <p>01 February 2024</p>	 <p>For NSCLC with &gt;1% PD-L1.</p> <p><i>IQWiG - A23-131</i></p> <p> <b>NOT APPROVED</b></p>



## Pharmacological Technologies




France



Ripretinib

Population:  
Adult

19 February 2024




For relapsed/refractory gastrointestinal stromal tumours.

*HAS - AP153*



Germany



Sacituzumab govitecan

Population:  
Adult

15 February 2024



For relapsed/refractory unresectable or metastatic ER+, HER2-breast cancer.

*IQWiG - A24-07*



Austria



Selpercatinib

Population:  
Adult and Adolescent  
≥12 years old

12 February 2024




Monotherapy for advanced RET fusion-positive thyroid cancer.

*AIHTA - 163*



Wales



Trastuzumab deruxtecan

Population:  
Unknown

14 February 2024



For HER2-low metastatic or unresectable breast cancer.

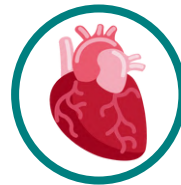
*AWTTC 4782*



## Pharmacological Technologies



### Cancer



### Cardiovascular

Germany



For relapsed/refractory metastatic colorectal cancer, with bevacizumab.

*IQWiG - A24-09*



Trifluridine/Tipiracil

Population:  
Unknown

15 February 2024

France



Prevention of recurrent attacks of hereditary angioedema.

*HAS - AP290*



Lanadelumab

Population:  
Children  
2 to 12 years

16 February 2024

Germany



For symptomatic (NYHA class II-III) hypertrophic obstructive cardiomyopathy.

*IQWiG - A23-132*



Mavacamten

Population:  
Adult

01 February 2024



## Pharmacological Technologies



### Endocrine



### Eye

Germany



Tirzepatide

For type 2 diabetes mellitus.

*IQWiG - A23-112*

Population:  
Adult



15 February 2024

Germany



Brolucizumab

For neovascular (wet) age-related macular degeneration.

*IQWiG - A23-101*

Population:  
Adult



01 February 2024

## Pharmacological Technologies



### Genitourinary



### Infection

Scotland



Difelikefalin

For moderate-to-severe pruritus in chronic kidney disease.

SMC 2623



Restricted approval

Population:  
Adult

12 February 2024

Brazil



Nirmatrelvir/  
Ritonavir

Population:  
Unknown  
Non-hospitalised  
high risk patients

01 February 2024

For COVID-19.

CONITEC



## Pharmacological Technologies



## Genetic/Metabolic


Germany



Cipaglucosidase alfa


Population:  
Adult

01 February 2024



For Pompe's disease.

*IQWiG - A23-79*




Germany



Migalastat


Population:  
Adult and  
Adolescent  
>12 years

15 February 2024



For Fabry disease.

*IQWiG - A24-10*




Germany



Migalastat


Population:  
Adult and  
Adolescent  
>12 years

15 February 2024



For Fabry disease ( $\alpha$ -galactosidase A deficiency).

*IQWiG - A23-88*



## Pharmacological Technologies



### Genetic/Metabolic


Germany



**Somapacitan**


Population:  
Unknown

01 February 2024



For growth hormone deficiency.

*IQWiG - G23-30*

 **APPROVED**

Orphan drug status


Germany



**Vosoritide**


Population:  
Adult, Adolescent  
and Children  
>2 years

15 February 2024



For achondroplasia.

*IQWiG - A24-08*

 **NOT APPROVED**

## Pharmacological Technologies



## Musculoskeletal


Germany



Baricitinib


Population:  
Children and  
Adolescent

15 February 2024



For refractory active  
enthesitis-associated  
arthritis.

*IQWiG - A23-114*

 **NOT APPROVED**


Germany



Baricitinib


Population:  
Children and  
Adolescent  
>2 years

15 February 2024



For refractory active  
juvenile psoriatic  
arthritis.

*IQWiG - A23-113*

 **NOT APPROVED**


Germany



Baricitinib


Population:  
Children and  
Adolescent  
≥2 years

15 February 2024



For active polyarticular  
juvenile idiopathic  
arthritis.

*IQWiG - A23-108*

 **NOT APPROVED**



## Pharmacological Technologies



## Neurology

Scotland



Ravulizumab

For neuromyelitis optica spectrum disorder.

SMC 2658



No submission received

Population:  
Adult

12 February 2024

Scotland



Ravulizumab

For generalised myasthenia gravis.

SMC 2657



No submission received

Population:  
Adult

12 February 2024

Brazil



Rivastigmine

For Parkinson's disease and dementia.

CONITEC

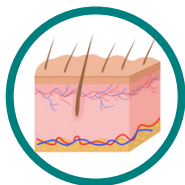


Recommended with a favourable opinion

Population:  
Unknown

01 February 2024

## Pharmacological Technologies



### Skin

Germany



Baricitinib

Population:  
Children  
≥2 years

15 February 2024

For atopic dermatitis.

*IQWiG - A23-109*



Scotland



Dupilumab

Population:  
Adult

12 February 2024

For moderate-to-severe  
prurigo nodularis.

*SMC 2598*



Scotland



Secukinumab

Population:  
Adult

12 February 2024

For active moderate-to-  
severe hidradentis  
suppurativa.

*SMC 2592*



Restricted approval

## Non-pharmacological Technologies



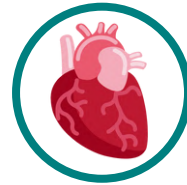
<p>South Korea</p>  <p>Laparoscopic endoscopic cooperative surgery</p> <p>Population: Unknown</p> <p>01 February 2024</p>	<p>For benign/malignant tumors of the gastrointestinal tract.</p> <p>NECA HTA-2024-2</p> <p></p>	<p>South Korea</p>  <p>Markerless real-time surface guided radiation therapy</p> <p>Population: Unknown</p> <p>01 February 2024</p>	<p>For extracorporeal radiation therapy.</p> <p>NECA HTA-2024-1</p> <p></p>
<p>South Korea</p>  <p>MRI-guided transurethral ultrasound ablation</p> <p>Population: Unknown</p> <p>01 February 2024</p>	<p>For localised prostate cancer.</p> <p>NECA HTA-2024-7</p> <p></p>	<p>Brazil</p>  <p>Radiofrequency thermal ablation</p> <p>Population: Unknown</p> <p>02 February 2024</p>	<p>For colon and rectal cancer with liver metastasis.</p> <p>CONITEC</p> <p></p>



## Non-pharmacological Technologies



### Cancer



### Cardiovascular

Spain



Radioguided surgery with I125-radioactive seeds

For non-palpable resectable breast, lung or thyroid cancer.

AETSA

Population: Unknown



22 February 2024

South Korea



Endograft fixation

For abdominal or thoracic aortic aneurysms.

NECA HTA-2024-3

Population: Unknown



01 February 2024

South Korea



Radiofrequency Catheter Ablation

For atrial fibrillation.

NECA HTA-2024-4

Population: Unknown



01 February 2024

## Non-pharmacological Technologies



### Genitourinary



### Mental Health

South Korea



MRI-guided  
transurethral  
ultrasound ablation

For prostatic  
hyperplasia.

NECA HTA-2024-6

Population:  
Unknown



01 February 2024

South Korea



Emotional freedom  
technique

For PTSD and acute  
stress reaction.

NECA HTA-2024-5

Population:  
Unknown



01 February 2024



## Non-pharmacological Technologies



### Pregnancy


Ireland



Birth cohort testing


Population:  
Children  
Newborn

09 February 2024



Antenatal hepatitis C testing.

HIQA



NOT APPROVED

## Diagnostic Technologies



## Cancer

Spain



Endobronchial  
ultrasonography

Population:  
Adult

26 February 2024

For diagnosing and/or  
staging lung cancer.

AQUAS



Brazil



Molecular testing

Population:  
Unknown

02 February 2024

For detection of HPV  
and cervical cancer.

CONITEC



Brazil



RT-PCR of EGFR

Population:  
Unknown

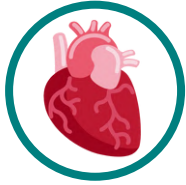
02 February 2024

For identification of  
epidermal growth factor  
receptor mutations in  
NSCLC.

CONITEC



## Diagnostic Technologies



### Cardiovascular



### Pregnancy

South Korea



AI-assisted 12-lead  
electrocardiography

For suspected acute  
myocardial infarction.

NECA PV-2024-1

Population:  
Unknown



01 February 2024

Brazil



Screening test for  
HTLV 1-2

For Human T-cell  
Lymphotropic Virus 1-2.

CONITEC

Population:  
Adult



02 February 2024

## Other Guidance



### Blood



### Cancer


Germany



Etranacogene dezaparvovec


Population:  
Unknown

01 February 2024




For haemophilia B.

*IQWiG - G23-99*




Germany



Odronextamab


Population:  
Adult

08 February 2024



For diffuse large B-cell lymphoma.

*IQWiG - I23-09*




Germany



Exagamglogen Autotemcel


Population:  
Unknown

01 February 2024



For beta-thalassaemia.

*IQWiG - A23-67*




Germany



Odronextamab


Population:  
Adult

08 February 2024

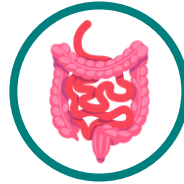


For follicular lymphoma.

*IQWiG - I23-08*



## Other Guidance



## Gastrointestinal

Spain



Biodegradable  
stents

Population:  
Unknown

15 February 2024

For benign oesophageal  
strictures.

AETS



Canada



Clinical and  
instrumental  
swallowing  
assessment

Population:  
Adult

23 February 2024

For patients with  
suspected dysphagia.

CADTH - RC1526-000



Canada



Tofacitinib and  
Other Drugs

Population:  
Adult

29 February 2024

For ulcerative colitis.

CADTH - OS0003-000





## Other Guidance



## Infection

Germany



**Dalbavancin**

Population:  
Unknown

15 February 2024



For acute bacterial skin and soft tissue infection.

*IQWiG - G23-31*




Canada



**Respiratory syncytial virus vaccines**

Population:  
Adult

26 February 2024




Evaluation of respiratory syncytial virus vaccines.

*CADTH - HE0047 -000*




England



**Vaccine for tuberculosis**

Population:  
Children  
Neonates with  $\geq 1$  parent/grandparent in high-incidence countries

16 February 2024

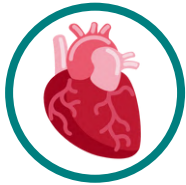


Prevention of tuberculosis.

*NICE - NG33*



## Other Guidance



### Cardiovascular

Spain



Implantable devices

Population:  
Unknown

15 February 2024

For left atrial appendage closure.

*AETS*



### Neurology

Spain



Exoskeleton

Population:  
Unknown

22 February 2024

For functional recovery of walking in CNS disorders such as MS, stroke and traumatic spinal injury.

*BOHTA*



## Other Guidance

### Other



### Pregnancy

Ireland



National rare disease strategies

Population:  
Unknown

08 February 2024

Rare diseases.

HIQA



Canada



Newborn screening

Population:  
Children  
Newborn

16 February 2024

To detect congenital adrenal hyperplasia.

INESSS



England



Selective gut decontamination

Population:  
Children

February 2024

In critically ill children.

NIHR





## 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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