

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

These decisions are categorised into one of four groups.

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

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



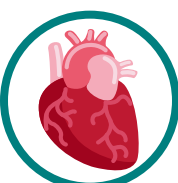
Blood

- Concizumab – France
- Vadadustat – Australia



Cancer

- Alectinib – Brazil
- Atezolizumab – Finland
- Belzutifan – Scotland
- Darolutamide – Scotland
- Dostarlimab – France
- Durvalumab – France
- Durvalumab – Germany
- Durvalumab – Germany
- Ivosidenib – Germany
- Ivosidenib – Germany
- Nivolumab – Germany
- Nivolumab – Germany
- Octreotide acetate and lanreotide – Brazil
- Olaparib – Scotland
- Olutasidenib – France
- Regorafenib – Scotland
- Trastuzumab deruxtecan – France
- Tremelimumab – Germany
- Tremelimumab and durvalumab – Germany
- Zanubrutinib – Scotland
- Zanubrutinib – Wales

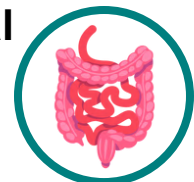


Cardiovascular

- Empagliflozin – Wales

Gastrointestinal

- Mirikizumab – Australia
- Mirikizumab – Germany
- Ustequinumab – Brazil



Genetic/Metabolic

- Avalglucosidase alfa – France
- Lumacraftor/ivacaftor – France
- Lumacraftor/ivacaftor – Germany



Infection

- Dengue vaccine 1, 2, 3 and 4 (attenuated) – Brazil
- Maribavir – Scotland
- Palivizumab – Brazil



Musculoskeletal

- Bimekizumab – Germany
- Bimekizumab – Germany
- Bimekizumab – Germany



Neurology

- Atogepant – Scotland
- Dimethyl fumarate – Germany
- Fenfluramine – Scotland
- Foslevodopa-foscarbidopa – Wales
- Ganaxolone – Wales

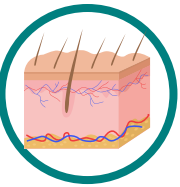


Genitourinary

- Voclosporin – Scotland



Pharmacological Technologies



Skin

- Dupilumab – France
- Dupilumab – France
- Dupilumab – Germany
- Secukinumab – Wales



Respiratory

- Riociguat – Germany

Other

- Semaglutide – France
- Semaglutide – Scotland

Non-pharmacological Technologies



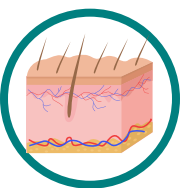
Cancer

- Axicabtagene ciloleucel - Germany
- Axicabtagene ciloleucel - Germany
- Axicabtagene ciloleucel - Germany
- Brexucabtagne autoleucel- Scotland
- Lutetium (177Lu) vipivotide tetraxetan - Scotland



Genetic/Metabolic

- Atidarsagene autotemcel - France



Skin

- Autologous micronized adipose tissue using 3D bio-printing - South Korea



Surgery

- Robot-assisted flexible ureterscopic stone removal surgery - South Korea

Diagnostic Technologies



Eye

- Artificial intelligence-based fundus examination - South Korea



Neurology

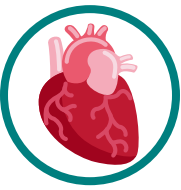
- Artificial intelligence computer-aided diagnosis from MRA images - South Korea
- Artificial intelligence-based computer aided diagnosis from CT images - South Korea

Other Guidance



Blood

- [Fidanacogene elaparvovec - Germany](#)
- [Diagnosis and management of jaundice - England](#)



Cardiovascular

- [Portable ECG - Norway](#)



Cancer

- [Niraparib - Canada](#)
- [Transperineal biopsy - Norway](#)
- [Gene-profiling test Oncotype DX - Norway](#)
- [Optical coherence tomography - Spain](#)
- [Circulating tumour DNA blood test - Spain](#)
- [Diagnosis and management of ovarian cancer - England](#)
- [143-gene panel - Canada](#)



Ear

- [Management of hearing loss - England](#)



Endocrine

- [Semaglutide - Canada](#)
- [Management of thyroid disease - England](#)

Eye



- [Refractive laser surgery - Canada](#)

Genetic/Metabolic

- [Expanded genetic analysis \(Thrombo incode\) - Spain](#)



Genitourinary

- [Penile traction therapy - Germany](#)
- [Management of urinary incontinence - England](#)



Infection

- [Nirsevimab - Canada](#)
- [T2 magnetic resonance platform - Spain](#)
- [Management of suspected acute respiratory infection - England](#)
- [Diagnosis and management of pneumonia - England](#)
- [Diagnosis and management of gonorrhoea and syphilis - Belgium](#)
- [Multiplex antigen near-patient tests - Ireland](#)

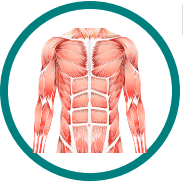


Mental health

- [Repetitive Transcranial Magnetic Stimulation Therapy \(rTMS\) - Spain](#)



Other Guidance



Musculoskeletal

- [Radiofrequency ablation - Canada](#)



Surgery

- [Robotic surgery - Spain](#)

Other

- [Opioids - Canada](#)
- [Paracetamol \(IV\) - Canada](#)
- [Point-of-care ultrasound - Canada](#)

Pharmacological Technologies



Blood

France



Concizumab

To prevent bleeding episodes in haemophilia A and B with anti-factor VIII or IX, as second-line treatment.

HAS - AP214



Early access authorisation

05 October 2023

Population:
Children
Over the age of 12

Australia



Vadadustat

Anaemia associated with chronic kidney disease in patients on chronic maintenance dialysis.

ATG - B03XA08



17 October 2023

Population:
Adult
Adults on chronic
maintenance dialysis

Pharmacological Technologies



Cancer

Brazil



Alectinib

First/second line therapy for locally advanced or metastatic non-small cell lung cancer with ALK rearrangements.

CONITEC



Population:
Unknown

04 October 2023

Finland



Atezolizumab

For adjuvant treatment after tumour resection for stage II to IIIa NSCLC with PD-L1 expression >50%.

FINCHTA



Population:
Adult

01 October 2023

Scotland



Belzutifan

For von Hippel-Lindau disease associated with renal cell carcinoma, CNS hemangioblastomas or pancreatic neuroendocrine tumours.

SMC2587



Population:
Adult

09 October 2023

Scotland



Darolutamide

For metastatic hormone-sensitive prostate cancer with docetaxel.

SMC2604




Population:
Adult

09 October 2023

Pharmacological Technologies



Cancer


<p>France</p>  <p>Dostarlimab</p> <p>Population: Adult Candidates for systemic treatment</p> <p>05 October 2023</p>	<p>For newly diagnosed or recurrent advanced endometrial cancer, in combination with platinum-based therapies.</p> <p><i>HAS - AP250</i></p> <p> APPROVED</p> <p>Early access authorisation</p>	<p>France</p>  <p>Durvalumab</p> <p>Population: Adult</p> <p>18 October 2023</p>	<p>First-line for unresectable or metastatic bile duct cancer with gemcitabine/cisplatin.</p> <p><i>HAS - AP252</i></p> <p> APPROVED</p> <p>Renewal of early access authorisation</p>
<p>Germany</p>  <p>Durvalumab</p> <p>Population: Adult</p> <p>05 October 2023</p>	<p>First line therapy for metastatic non-small cell lung cancer without EGFR/ALK mutations.</p> <p><i>IQWiG - A23-31</i></p> <p> NOT APPROVED</p>	<p>Germany</p>  <p>Durvalumab</p> <p>Population: Adult</p> <p>05 October 2023</p>	<p>First line therapy for unresectable or metastatic biliary tumour with cisplatin and gemcitabine.</p> <p><i>IQWiG - A23-26</i></p> <p> APPROVED</p>

Pharmacological Technologies



Cancer


Germany



Ivosidenib


Population:
Adult
Standard
chemotherapy is not
suitable

16 October 2023




For newly-diagnosed
acute myeloid
leukaemia with IDH1-
R132 mutation with
azacitadine.

IQWiG - G23-16

 **APPROVED**

Orphan drug status


Germany



Ivosidenib


Population:
Adult

16 October 2023




Monotherapy of locally
advanced or metastatic
cholangiocarcinoma
with IDH1-R132
mutation.

IQWiG - G23-15

 **APPROVED**

Orphan drug status


Germany



Nivolumab


Population:
Adolescent
Aged 12 years or
older

02 October 2023



Monotherapy for
adjuvant treatment of
advanced/metastatic
melanoma.

IQWiG - A23-59

 **NOT APPROVED**


Germany



Nivolumab


Population:
Adolescent
Aged 12 years or
older

02 October 2023



For advanced or
metastatic melanoma.

IQWiG - A23-58

 **NOT APPROVED**

Pharmacological Technologies



Cancer

Brazil



Octreotide acetate
and lanreotide

For functional
gastroenteropancreatic
endocrine tumours.

COINTEC



Population:
Unknown

04 October 2023

Scotland



Olaparib

Second line therapy for
HER2 negative, high-
risk early breast cancer
with germline BRCA1/2-
mutations.

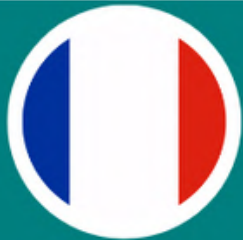
SMC2518



Population:
Adult

09 October 2023

France



Olutasidenib

For relapsed or
refractory acute myeloid
leukaemia with IDH1
mutation.

HAS - AP256



Population:
Adult

18 October 2023

Scotland



Regorafenib

Second line therapy for
metastatic colorectal
cancer.

SMC2562



Population:
Adult

09 October 2023

Pharmacological Technologies



Cancer

France



Trastuzumab
deruxtecan

Population:
Adult

30 October 2023

For recurrent,
advanced/metastatic
HER2- breast cancer.

HAS - AP268



Renewal of early access
authorisation

Germany



Tremelimumab

Population:
Adult

05 October 2023

First line therapy for
metastatic non-small
cell lung cancer without
EGFR/ ALK mutations.

IQWiG - A23-29



Germany



Tremelimumab and
durvalumab

Population:
Adult

05 October 2023

First line therapy for
metastatic non-small
cell lung cancer without
EGFR/ ALK mutations.

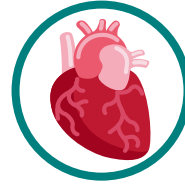
IQWiG - A23-84



Pharmacological Technologies



Cancer



Cardiovascular

Scotland



Zanubrutinib

Monotherapy for chronic lymphocytic leukaemia.

SMC2600

Population:
Adult



Approved for restricted use

09 October 2023

Wales



Empagliflozin

For symptomatic chronic heart failure with preserved or mildly reduced ejection fraction.

AWTTC - 4811

Population:
Adult



Excluded due to NICE appraisal - TA929

05 October 2023

Wales



Zanubrutinib

For relapsed/refractory chronic lymphocytic leukaemia.

AWTTC - 5201

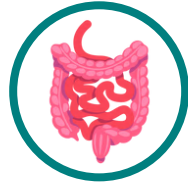
Population:
Adult



Excluded due to NICE appraisal - ID5078

12 October 2023

Pharmacological Technologies



Gastrointestinal

Australia



Mirikizumab

For refractory moderate to severe ulcerative colitis.

ATG



Population:
Adult

11 October 2023

Germany



Mirikizumab

For refractory moderate to severe ulcerative colitis.

IQWiG - A23-73



Population:
Adult

16 October 2023

Brazil



Ustequinumab

For refractory moderate to severe active Crohn's disease.

COINTEC



Population:
Unknown

04 October 2023

Pharmacological Technologies



Genetic/Metabolic


France



Avalglucosidase alfa


Population:
Adult, Adolescent
and Children
≥6 months

12 October 2023



For Pompe disease after failure of alglucosidase alfa.

HAS - AP253



Renewal of early access authorisation


France



**Lumacraftor/
ivacaftor**


Population:
Children
>1 year to <2 years old

25 October 2023



For cystic fibrosis, homozygous for F508del mutation of the CFTR gene.

HAS - AP265



Early access authorisation

Germany



**Lumacraftor/
ivacaftor**

Population:
Children
1 to <2 years old

16 October 2023

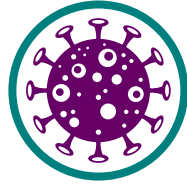


For cystic fibrosis, homozygous for F508del mutation of CFTR gene.

IQWIG - A23-72



Pharmacological Technologies



Infection

Brazil



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

Population:
Adult, Adolescent and Children
Aged 4 to 60 years old

05 October 2023

For dengue prevention.

COINTEC



Scotland



Maribavir

Population:
Adult
Patients who have undergone a haematopoietic stem cell transplant or solid organ transplant

09 October 2023

For refractory cytomegalovirus infection and/or disease.

SMC2576



Brazil



Palivizumab

Population:
Children
Premature children with gestational ages 29 to 31 weeks and 6 days

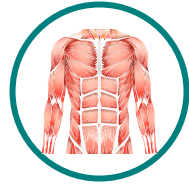
04 October 2023

For prevention of respiratory syncytial virus infection.

COINTEC



Pharmacological Technologies



Musculoskeletal

Germany



Bimekizumab

Population:
Adult

02 October 2023

For active non-radiographic inflammatory axial spondyloarthritis.

IQWIG - A23-62



Germany



Bimekizumab

Population:
Adult

02 October 2023

For active ankylosing spondylitis.

IQWIG - A23-61



Germany



Bimekizumab

Population:
Adult

02 October 2023

Second line therapy for active psoriatic arthritis.

IQWIG - A23-60



Pharmacological Technologies



Neurology

Scotland



Atogepant

For prophylaxis of migraine and episodic migraine.

SMC2599



Population:
Adult

09 October 2023

Germany



Dimethyl fumarate

Population:
Children and
Adolescent
≥ 13 to < 18 years

IQWiG - A23-68



16 October 2023

Scotland



Fenfluramine

For seizures associated with Dravet syndrome.

SMC2569



Population:
Children
≥ 2 years old

09 October 2023

Wales



Foslevodopa-
foscarbidopa

Population:
Adult

AWTTC - 4661



20 October 2023

Excluded due to NICE appraisal - ID3876

Pharmacological Technologies



Neurology

Wales



Ganaxolone

Population:
Other
Children,
adolescents and
young adults, aged \geq
2 years old

16 October 2023

For seizures in
genetically confirmed
CDKL5 gene mutation.

AWTTC - 4830



Excluded due to NICE
appraisal - ID3988



Genitourinary

Scotland



Voclosporin

Population:
Adult

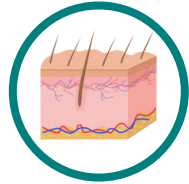
09 October 2023

For active class III, IV or
V lupus nephritis with
mycophenolate mofetil.

SMC2570



Pharmacological Technologies



Skin


France



Dupilumab


Population:
Adult
Requiring systemic therapy

03 October 2023



For moderate to severe nodular prurigo.

HAS - AP240



Renewal of early access approval


France



Dupilumab


Population:
Children
Aged 6 months to 5 years for systemic treatment

12 October 2023



For severe atopic dermatitis.

HAS - AP264



Renewal of early access authorisation


Germany



Dupilumab


Population:
Adult

05 October 2023




For moderate to severe prurigo nodularis.

IQWIG - A23-82



NOT APPROVED


Wales



Secukinumab


Population:
Adult

20 October 2023



For refractory hidradenitis suppurativa.

AWTTC - 4318



EXCLUDED

Excluded due to NICE appraisal - ID4039

Pharmacological Technologies



Respiratory

Other

Germany



Riociguat

Population:
Children and
Adolescent
<18 years old and
body weight of ≥ 50
kg

02 October 2023

For class II/III
pulmonary arterial
hypertension.

IQWiG - A23-57



France



Semaglutide

Population:
Adult
With BMI ≥ 40 kg/m²

02 October 2023

For morbid obesity and
at least one related
comorbidity.

HAS-AP273



Withdrawn by
manufacturer

Scotland



Semaglutide

Population:
Adult

09 October 2023

For adults with obesity
or overweight with 1+
weight-related
comorbidity.

SMC2497



Approved for restricted
use

Non-pharmacological Technologies



Cancer


Germany



Axicabtagene ciloleucel

Population:
Adult

02 October 2023



Third plus line therapy for relapsed/refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma.

IQWiG - A23-65

NOT APPROVED


Germany



Axicabtagene ciloleucel

Population:
Adult

02 October 2023



Second line therapy for relapsed/refractory diffuse large B cell lymphoma or high-grade B-cell lymphoma.

IQWiG - A23-66

NOT APPROVED


Germany



Axicabtagene ciloleucel

Population:
Adult

02 October 2023



Fourth plus line therapy for relapsed or refractory follicular lymphoma.

IQWiG - A23-63

NOT APPROVED


Scotland



Brexucabtagne autoleucel

Population:
Adult
26 years or older

09 October 2023



For relapsed/refractory B-cell precursor acute lymphoblastic leukaemia.

SMC2548

APPROVED

Non-pharmacological Technologies



Cancer



Genetic/Metabolic

Scotland



Lutetium (¹⁷⁷Lu)
vipivotide tetraxetan

Population:
Adult

09 October 2023

Second line therapy for prostate specific membrane antigen-positive metastatic castration-resistant prostate cancer.

SMC2517



France



Atidarsagene
autotemcel

Population:
Children
Asymptomatic children with late infantile or juvenile early-onset forms of the disease
06 October 2023

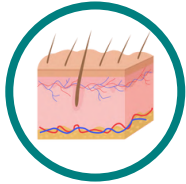
For metachromatic leukodystrophy with reduction in enzymatic activity of arylsulfatase A.

HAS - AP254



Renewal of early access authorisation

Non-pharmacological Technologies



Skin



Surgery

South Korea



Autologous
micronized adipose
tissue using 3D
bio-printing

For treatment of
refractory diabetic
wounds and foot ulcers.

NHTA - PV-2023-9



Population:
Unknown

13 October 2023

South Korea



Robot-assisted
flexible ureterscopic
stone removal
surgery

For urinary stones.

NHTA - PV-2023-11



Population:
Unknown

13 October 2023

Diagnostic Technologies



Eye



Neurology

South Korea



Artificial intelligence-based fundus examination

For diagnosis of age-related macular degeneration, diabetic retinopathy, glaucoma.

NHTA - PV-2023-10

Population: Unknown



13 October 2023

South Korea



Artificial intelligence computer-aided diagnosis from MRA images

For cerebral aneurysm detection.

NHTA - PV-2023-8

Population: Unknown



13 October 2023

South Korea



Artificial intelligence-based computer aided diagnosis from CT images

For intracerebral haemorrhage detection.

NHTA - PV-2023-7

Population: Unknown

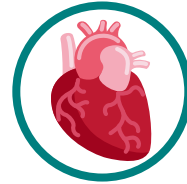


13 October 2023

Other Guidance



Blood



Cardiovascular

Germany



Fidanacogene
elaparvovec

For haemophilia B.

IQWiG - I23-06

Population:
Adult, Adolescent
and Children



16 October 2023

Norway



Portable ECG

For diagnosis of atrial
fibrillation.

NIPH

Population:
Unknown



26 October 2023

England



Diagnosis and
management of
jaundice

To detect or prevent
very high levels of
bilirubin.

NICE - CG98

Population:
Children
Newborn babies
under 28 days



31 October 2023


Update of guidance

Other Guidance



Cancer


Canada



Niraparib


Population:
Unknown

05 October 2023




Ovarian cancer.

CADTH - OS0002-000




Norway



Transperineal biopsy


Population:
Unknown

04 October 2023




For prostate cancer detection.

NIPH



Update of a 2022 HTA


Norway



**Gene-profiling test
Oncotype DX**


Population:
Unknown

10 October 2023




To predict recurrence and treatment response in breast cancer.

NIPH




Spain



Optical coherence tomography


Population:
Unknown

October 2023



To evaluate tumour margins during breast cancer surgery.

AETSA



Other Guidance



Cancer

Spain



Circulating tumour
DNA blood test

For the identification
and location of different
cancers.

AQUAS

Population:
Adult

25 October 2023



England



Diagnosis and
management of
ovarian cancer

For detecting,
diagnosing and treating
epithelial ovarian
cancer, fallopian tube
cancer, primary
peritoneal cancer or
borderline ovarian
cancer.

NICE - CG122

Population:
Adult

02 October 2023



Update of guidance

Canada



143-gene panel

To detect myeloid
cancers.

INESSS

Population:
Unknown

24 October 2023



Other Guidance



Ear



Endocrine

England



Management of hearing loss

Population:
Adult
Aged 18 and over

02 October 2023

For hearing loss in primary, community and secondary care.

NICE - NG98



Update of guidance

Canada



Semaglutide

Population:
Adult

19 October 2023

For type 2 diabetes.

CADTH - RC1507-000



England



Management of thyroid disease

Population:
Adult, Adolescent
and Children

12 October 2023

Investigating and managing thyroid disease.

NICE - NG145



Update of guidance

Other Guidance



Eye



Genetic/Metabolic

Canada



Refractive laser surgery

For visual refraction conditions.

CADTH - RC1514-000

Population:
Unknown



26 October 2023

Spain



Expanded genetic analysis
(Thrombo incode)

To identify and grade risks of venous thromboembolism and/or recurrent spontaneous miscarriage.

IACS

Population:
Adult



October 2023

Other Guidance



Genitourinary



Infection

Germany



Penile traction therapy

For induratio penis plastica.

IQWiG - N22-01

Population:
Adult



26 October 2023

Canada



Nirsevimab

For prevention of respiratory syncytial virus infection.

CADTH - HE0045-000

Population:
Children
Infants



19 October 2023

England



Management of urinary incontinence

Guidance on symptomatic treatments in neurological conditions.

NICE - CG148

Population:
Adult, Adolescent
and Children



02 October 2023

Update of guidance

Spain



T2 magnetic resonance platform

For diagnosis of invasive candida infection.

AETSA

Population:
Children and
Adolescent



October 2023

Other Guidance



Infection


England



Management of suspected acute respiratory infection

Population:
Adult
Aged 16 and over

31 October 2023



Assessment of symptoms and signs of acute respiratory infection (bacterial or viral) at first remote or in-person contact.


NICE - NG237



EVIDENCE REVIEW

New guidance


England



Diagnosis and management of pneumonia

Population:
Adult
Adults who do not have COVID-19

31 October 2023



To improve accurate assessment and diagnosis of pneumonia to guide antibiotic prescribing.

NICE - CG191



EVIDENCE REVIEW

Update of guidance


Belgium



Diagnosis and management of gonorrhoea and syphilis

Population:
Adult and Adolescent

19 October 2023



Information and best practices on gonorrhoea and syphilis management for a primary care physician.

KCE Report 371Cs



EVIDENCE REVIEW


Ireland



Multiplex antigen near-patient tests

Population:
Adult
Suspected respiratory tract infection

31 October 2023



To detect SARS-CoV-2, influenza and/or respiratory syncytial virus (RSV) in residential and primary care settings.

HIQA



EVIDENCE REVIEW

Other Guidance



Mental Health

Spain



Repetitive
Transcranial
Magnetic Stimulation
Therapy (rTMS)

Population:
Adult
Aged 27 to 65 years

October 2023

For refractory major
depressive disorder.

ATESA



Musculoskeletal

Canada



Radiofrequency
ablation

Population:
Adult

11 October 2023

For chronic knee, hip
and shoulder pain.

CADTH - RC1504-000



Other Guidance



Surgery


Spain



Robotic surgery

Population:
Adult, Adolescent
and Children

04 October 2023



In general, urology,
digestive,
cardiothoracic,
gynecology,
endocrinology,
opthamology and head
and neck surgery.


AQUAS



Other Guidance

Other


Canada



Opioids


Population:
Adult

05 October 2023



Treatment for chronic pain in patients with or with a history of opioid use disorder.

CADTH - RE0045-000



EVIDENCE REVIEW


Canada



Paracetamol (IV)


Population:
Adult

06 October 2023




For moderate to severe acute pain in emergency departments.

CADTH - RC1508-000



EVIDENCE REVIEW


Canada



Point-of-care ultrasound


Population:
Adult

16 October 2023



For central venous line catheter insertion.

CADTH - RC1509-000



EVIDENCE REVIEW

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
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