

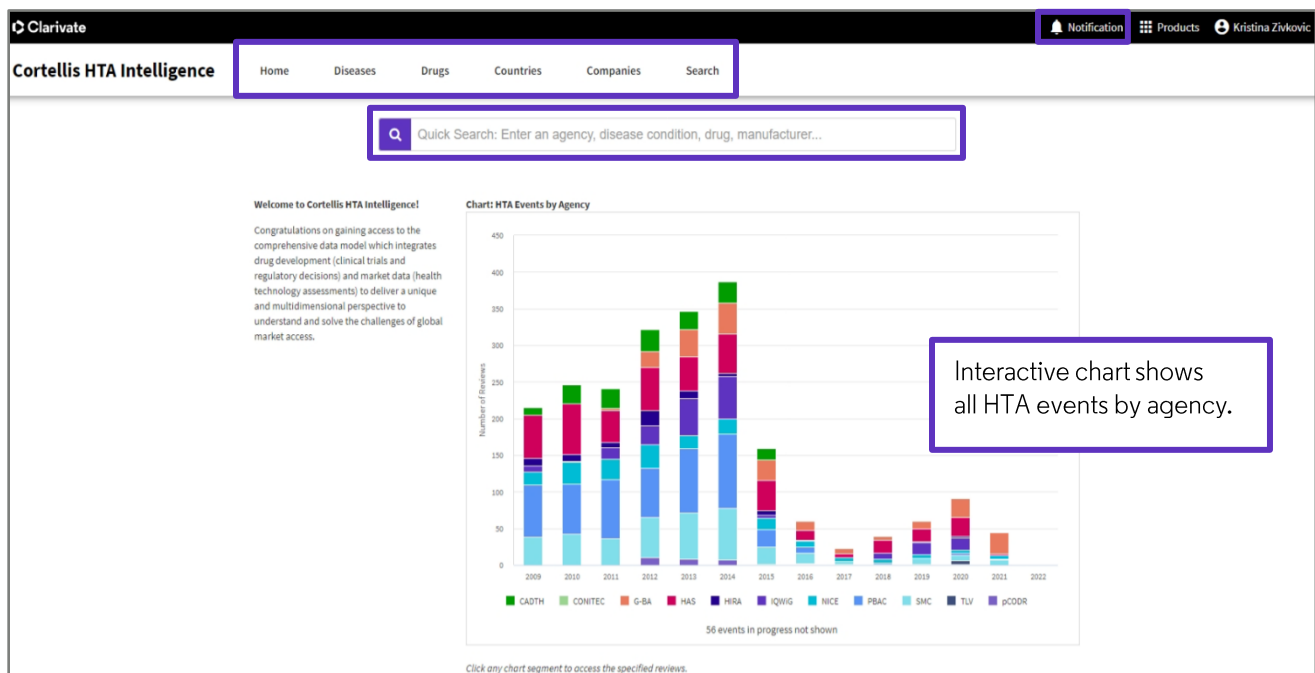
Getting Started Guide

Cortellis HTA Intelligence

Monitor the industry, keep track of your competition, detect potential trends, and identify market opportunities in the reimbursement and regulatory landscape. Cortellis HTA Intelligence covers HTA data for 21 markets and marketing authorization data from 5 regulatory agencies globally covering 70+ disease conditions across 8 therapeutic areas.

Use Cortellis HTA Intelligence to quickly understand the HTA decision landscape for a drug, disease condition, country, agency, or company and determine the key clinical and economic rationales between decision-making. You can also receive HTA decision notifications delivered directly to your email using Notifications.

1. After signing in, you will arrive at the **Dashboard**.
2. You may enter the data by:
 - a. Accessing the black menu bar to **Browse by Diseases, Drug, Countries or Companies**
 - b. Clicking on **Search** to utilize filters to narrow down by specific events: Reimbursement, Label, or Managed Entry Agreements, as well as other criteria.
 - c. Selecting **Notifications** to view brand new decisions plus those you are tracking.
 - d. Entering a term in **Quick Search**.



Example: Find events for Acute Myeloid Leukemia using Quick Search

1. Begin **typing into the search bar** and choose from the suggestions.

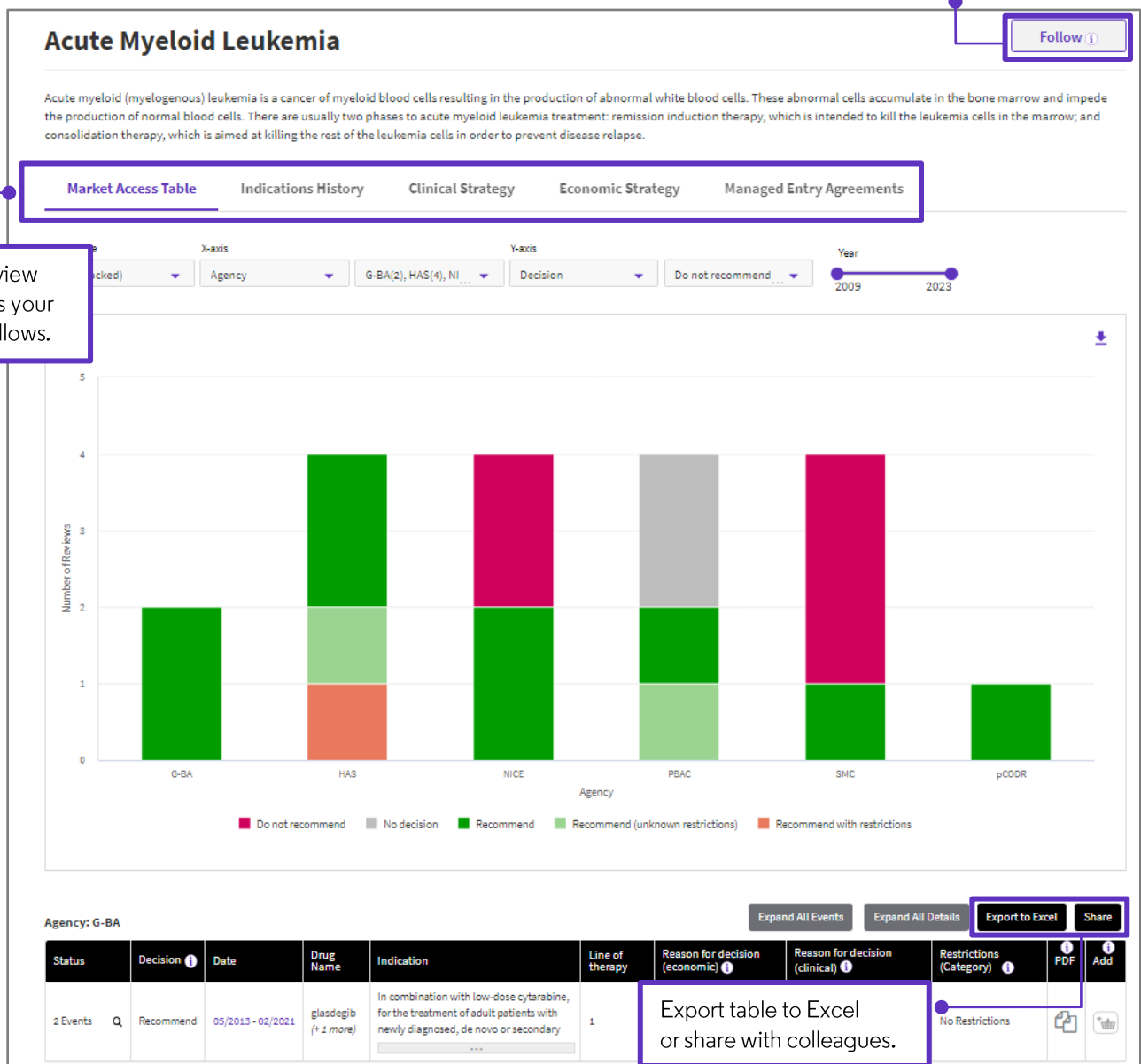
Search all documents for acute my

Disease Conditions

Acute Myeloid Leukemia

Follow to create email notifications on a Disease, Drug, Company, Country, or Agency.

2. The **Market Access Table** provides a graphical overview of Acute Myeloid Leukemia with detail on the events below including links to original documents from the agencies.



Download the Chart with your saved preferences and criteria.

Acute Myeloid Leukemia

Follow (1)

Acute myeloid (myelogenous) leukemia is a cancer of myeloid blood cells resulting in the production of abnormal white blood cells. These abnormal cells accumulate in the bone marrow and impede the production of normal blood cells. There are usually two phases to acute myeloid leukemia treatment: remission induction therapy, which is intended to kill the leukemia cells in the marrow; and consolidation therapy, which is aimed at killing the rest of the leukemia cells in order to prevent disease relapse.

Market Access Table

Indications History

Clinical Strategy

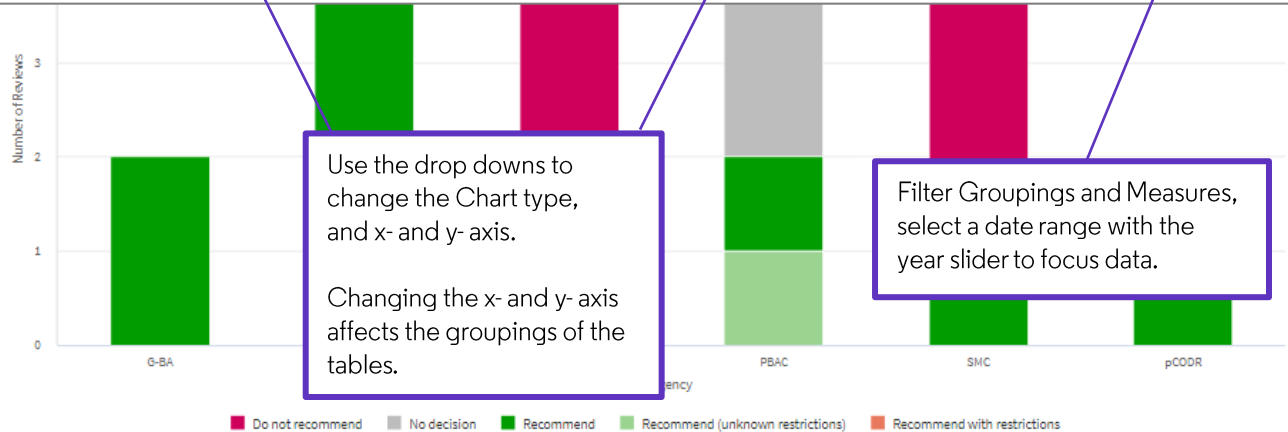
Economic Strategy

Managed Entry Agreements

Chart Type: Bar (Stacked) X-axis: Agency Y-axis: Decision Year: 2009 - 2023



Chart Type: Bar (Stacked) X-axis: Agency Y-axis: Decision Year: 2009 - 2023



Use the drop downs to change the Chart type, and x- and y- axis.

Changing the x- and y- axis affects the groupings of the tables.

Filter Groupings and Measures, select a date range with the year slider to focus data.

Agency: G-BA

Expand All Events

Expand All Details

Export to Excel

Share

Status	Decision ⓘ	Date	Drug Name	Indication	Line of therapy	Reason for decision (economic) ⓘ	Reason for decision (clinical) ⓘ	Restrictions (Category) ⓘ	PDF ⓘ	Add ⓘ
2 Events Q	Recommend	05/2013 - 02/2021	glasdegib (+ 1 more)	In combination with low-dose cytarabine, for the treatment of adult patients with newly diagnosed, de novo or secondary	1	N/A	Greater efficacy/effectiveness (+ 1 more)	No Restrictions		

3. The **Event table** below uses a funnel approach to reveal increasing amounts of information on each event.

Agency: G-BA

Expand All Events

Expand All Details

Export to Excel

Share

Click a row to reveal individual events, then click an event row to reveal more details.

Drug Name	Indication	Line of therapy	Reason for decision (economic)	Reason for decision (clinical)	Restrictions (Category)	PDF	Add
gemtuzumab ozogamicin (more)	In combination with low-dose cytarabine, for the treatment of adult patients with newly diagnosed, de novo or secondary	1	N/A	Greater efficacy/effectiveness (+ 1 more)	No Restrictions		

Agency: HAS

Status	Decision	Date	Drug Name	Indication	Line of therapy	Reason for decision (economic)	Reason for decision (clinical)	Restrictions (Category)	PDF	Add
2 Events	Recommend	12/2010 - 07/2020								
		07/2020	gemtuzumab ozogamicin	For the treatment of adults and children aged ≥ 2 years with CD33-positive, relapsed or refractory AML, except acute	2+	N/A	Acceptable efficacy/effectiveness	No Restrictions		
		12/2010	histamine dihydrochloride	Ceplene maintenance therapy is indicated for adult patients with AML in first remission concomitantly treated with interleukin-2.	Maintenance	N/A	Acceptable efficacy/effectiveness	No Restrictions		

HAS ASMR

5

Decision reason - clinical (details)

In the total study population, the combination of Ceplene + interleukin-2 was 324 days in the Ceplene + interleukin-2 group vs. 264 days in the untreated group, which is an absolute difference in OS between the two groups, either in the total groups or in the subgroups. The Committee stressed that the results of the study are based on a small number of patients and cannot be ascribed to the combination of Ceplene + interleukin-2. In view of the methodological weaknesses of the presented study, but bearing in mind both the absence of any pharmacological alternative and also the effect observed compared to current management, the Transparency Committee provided a moderate actual benefit to the combination, Ceplene + interleukin-2.

Is the review an update or resubmission?

No

French Reimbursement Rate

Not reported.

Actual Benefit (SMR)

Moderate

Dosage

Ceplene is administered one - three minutes after each injection of interleukin-2. Each 0.5 mL Ceplene dose is injected slowly over five -15 minutes. Ceplene and interleukin-2 treatment cycles are administered for 10 treatment cycles: each cycle consists of a treatment period of 21 days (three weeks) followed by a three- or six-week treatment-free period. For cycles one - three, each cycle consists of three weeks of treatment followed by a three-week treatment-free period. For cycles four - 10, each cycle consists of three weeks of treatment followed by a six-week treatment-free period.

Label Indication

EMA Label (October 2008): Ceplene maintenance therapy is indicated for adult patients with acute myeloid leukaemia (AML) in first remission who are being concomitantly treated with interleukin-2. The efficacy of Ceplene has not been fully demonstrated in patients >60 years of age.

Click on a date to open the full event details.

View original agency documents from the PDF column.

The gear icon indicates documents can be translated using Google translate.

1 Event	Recommend (unknown restrictions)	04/2014	daunorubicin	For the treatment of AML in children, as part of a combination chemotherapy regimen.	1	N/A	Acceptable efficacy/effectiveness	Label unavailable		
1 Event	Recommend with restrictions	07/2020	gemtuzumab ozogamicin	For the treatment of adult patients with AML who have an FLT3 mutation and are preferably eligible for treatment with gi	1+	N/A	Acceptable efficacy/effectiveness	Population		

Click a row to reveal individual events, then click an event row to reveal more details.

Click on a date to open the full event details.

View original agency documents from the PDF column.

The gear icon indicates documents can be translated using Google translate.

4. Click the **Add to basket icon** to compare up to 4 decisions side by side.

Agency: HAS

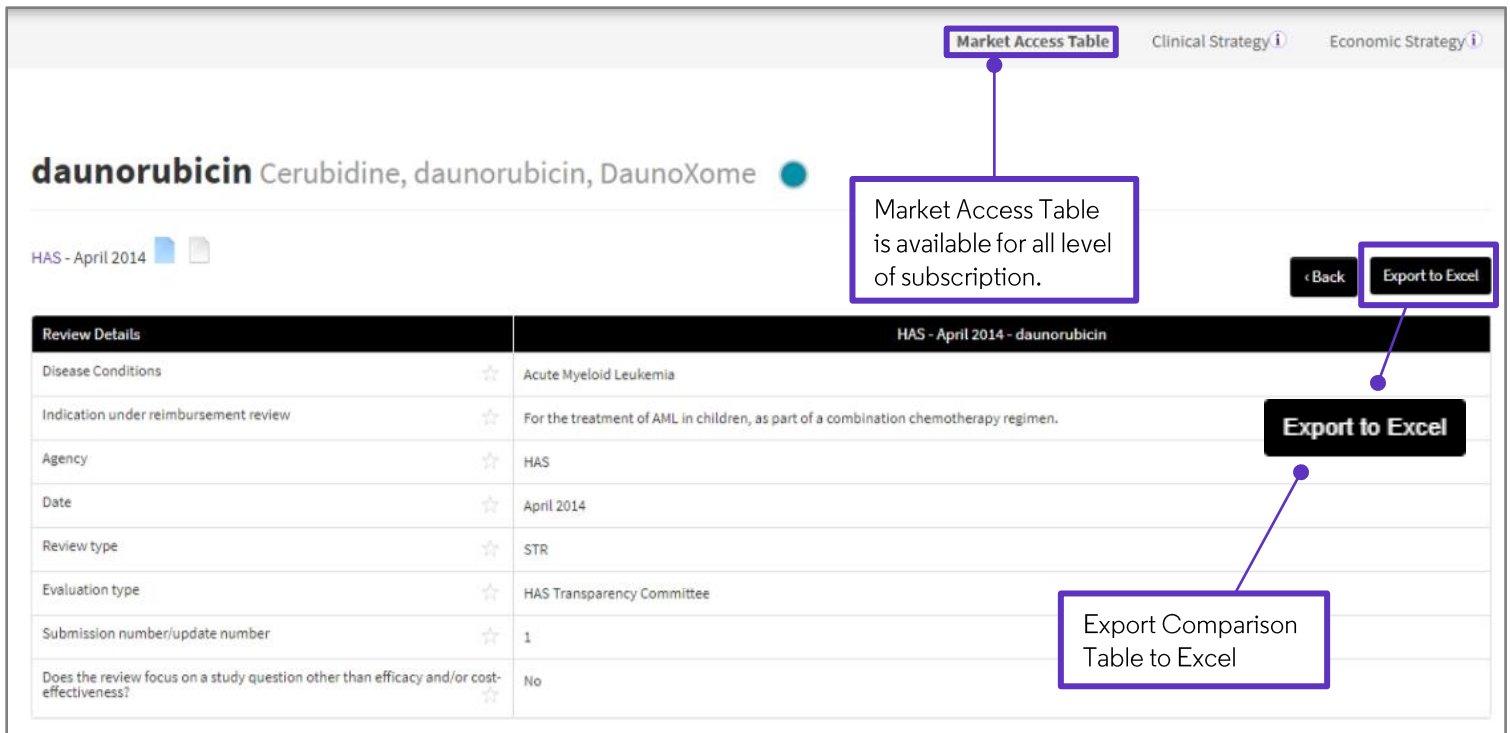
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Add to basket

Then scroll to the top of the page to view selections and click **Compare**.

Acute Myeloid Leukemia	gemtuzumab ozogamicin	HAS	July 2020		
Acute Myeloid Leukemia	histamine dihydrochloride	HAS	December 2010		
Acute Myeloid Leukemia	daunorubicin	HAS	April 2014		
Acute Myeloid Leukemia	gemtuzumab ozogamicin	HAS	July 2020		
					(4)
				Compare >	

- You can choose to compare data from the Market Access Table, Clinical Strategy or Economic Strategy as your account permissions allow.



Market Access Table Clinical Strategy Economic Strategy

daunorubicin Cerubidine, daunorubicin, DaunoXome

HAS - April 2014

Market Access Table is available for all level of subscription.

Export to Excel

Export Comparison Table to Excel

Review Details	HAS - April 2014 - daunorubicin	
Disease Conditions	☆	Acute Myeloid Leukemia
Indication under reimbursement review	☆	For the treatment of AML in children, as part of a combination chemotherapy regimen.
Agency	☆	HAS
Date	☆	April 2014
Review type	☆	STR
Evaluation type	☆	HAS Transparency Committee
Submission number/update number	☆	1
Does the review focus on a study question other than efficacy and/or cost-effectiveness?	☆	No

[Market Access Table ⓘ](#)
[Clinical Strategy](#)
[Economic Strategy ⓘ](#)

daunorubicin

Cerubidine, daunorubicin, DaunoXome

HAS - April 2014

[« Back](#)
[Export to Excel](#)

Review Details	
Disease Conditions	☆ Acute Myeloid Leukemia
Indication under reimbursement review	☆ For the treatment of AML in children, as part of a combination
Agency	☆ HAS
Date	☆ April 2014

Evidence Information	HAS - April 2014 - daunorubicin
Comparators	☆ Autologous stem cell transplant (ASCT) drugs
Evidence sources cited by the review	☆ The publications on the treatment of childhood AML submitted by the company are: an open-label, randomised study comparing the efficacy of consolidation with haematopoietic stem cell transplantation with intensive chemotherapy (POG 8821); two non-comparative studies evaluating combination chemotherapy regimens (AML-87 and POG 8498); four reviews of a number of studies from the AIEOP (Italy), CCG (United States), and BFM (Germany) groups of trials evaluating successive chemotherapy protocols. These studies will not be discussed here because of the type of publications; a post-hoc study evaluating the efficacy of the APL-93 protocol will not be discussed here because of its methodology. The company also provided the five most recent periodic safety update reports covering the period from 04/01/1994 - 03/31/2012.
Details on population included in the evidence sources	☆ AML-87: Children with newly diagnosed and non-pretreated AML, secondary AML, or AML associated with myelodysplastic syndromes, included between 1984 and 1988. POG 8821: Children <21 years of age with non-pretreated AML or isolated myeloid sarcoma, in remission after induction therapy, diagnosed in the United States between 1988 and 1993. POG 8498: Children <21 years of age with non-pretreated AML, diagnosed in the United States between 1984 and 1988.
Does the review focus on a study question other than efficacy and/or cost-effectiveness?	☆ No

Compare **Clinical Strategy** and **Economic Strategy** details according to your subscription entitlements.

Clinical Strategy is the example shown.

For more information contact Customer Service at [LS Product Support](#)