NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Decitabine–cedazuridine with venetoclax for untreated acute myeloid leukaemia when intensive induction chemotherapy is unsuitable

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of decitabine–cedazuridine with venetoclax within its marketing authorisation for treating newly diagnosed acute myeloid leukaemia when induction chemotherapy is unsuitable.

Background

Acute myeloid leukaemia (AML) is a cancer of the blood and bone marrow. It is characterised by the overproduction of early immature myeloid cells (blasts), which build up in the blood and bone marrow, interfering with normal blood cell production. AML progresses quickly over weeks or months and is fatal if not treated. Symptoms of AML include anaemia, bleeding problems, and serious infections. People with AML also feel fatigued, which can affect daily life.

In 2023, there were around 2,500 new cases of AML in England, with the highest incidence in people aged 85 to 89.[1,2] The 5-year survival rate of AML for people diagnosed in England between 2013 and 2016 was around 20 to 23%, but varies with age.[3]

People who are fit enough can have intensive treatment for AML, which aims to cure it. It is done in 2 phases: induction chemotherapy to reduce the number of blast cells, then consolidation chemotherapy to reduce the risk of recurrence. For people with good general health, the treatment options are intensive chemotherapy and allogeneic haematopoietic stem cell transplant (HSCT).

Over half of patients with AML are ineligible for intensive chemotherapy and HSCT because of factors such as age or comorbidities. Other treatment options for this population include azacitidine, ivosidenib, low dose cytarabine and venetoclax. Most people with untreated AML who cannot have intensive induction chemotherapy have venetoclax with azacitidine in clinical practice. The aim of non-intensive treatment options is to control symptoms and improve quality of life.

NICE technology appraisal guidance 765 recommends venetoclax with azacitidine for untreated AML in adults when intensive chemotherapy is unsuitable.

NICE technology appraisal guidance 787 recommends venetoclax with low dose cytarabine for untreated AML in adults when intensive chemotherapy is unsuitable, if they have over 30% bone marrow blasts.

NICE technology appraisal guidance 979 recommends ivosidenib plus azacitidine as an option for untreated AML with an IDH1 R132 mutation in adults who cannot have standard intensive induction chemotherapy.

The technology

Decitabine-cedazuridine (Inaqovi, Otsuka Pharmaceutical) with venetoclax (Venclyxto, AbbVie) does not currently have a marketing authorisation in the UK for AML. It has been studied in a single arm clinical trial in adults with AML who are ineligible for intensive induction chemotherapy.

Decitabine-cedazuridine has a marketing authorisation as monotherapy for the treatment of adult patients with newly diagnosed AML who are ineligible for standard induction chemotherapy.

Intervention(s)	Decitabine–cedazuridine with venetoclax
Population(s)	Adults with newly diagnosed acute myeloid leukaemia in whom intensive induction chemotherapy is not suitable
Subgroup(s)	• Proportion of bone marrow blasts (over 30%) • IDH1 R132 mutation status
Comparators	• Venetoclax with azacitidine • Venetoclax with low dose cytarabine (for adults with over 30% bone marrow blasts) • Ivosidenib with azacitidine (for adults with an IDH1 R132 mutation)
Outcomes	The outcome measures to be considered include: • overall survival • event-free survival • disease-free survival • response rates, including remission • blood transfusion dependence • rate of complete remission and complete remission with partial haematologic recovery • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Ivosidenib with azacitidine for untreated acute myeloid leukaemia with an IDH1 R132 mutation (2024). NICE technology appraisal guidance 979. Venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable (2022) NICE technology appraisal guidance 787. Venetoclax with azacitidine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable (2022) NICE technology appraisal guidance 765. **Related NICE guidelines:** Haematological cancers: improving outcomes (2016) NICE guideline NG47. **Related quality standards:** Haematological cancers (2017) NICE quality standard 150

References

1. NHS Digital (2025). Cancer registration statistics in England, 2023. Accessed February 2026.

2. Cancer Research UK (2023). Survival for acute myeloid leukaemia (AML). Accessed February 2026.

3. National Disease Registration Service (2023) – Get Data Out programme. Accessed February 2026.