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 [ID6601]
Response to stakeholder organisation comments on the draft remit and draft scope

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Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Otsuka Pharmaceuticals UK (company)	The proposed evaluation route (cost-comparison) is appropriate and is described in further detail in Questions for Consultation below.	Thank you for your comment. Following final scope sign off, this topic has been selected for cost comparison.
	Royal College of Pathologists	The proposed evaluation route is valid and appropriate for this topic.	Thank you for your comment. No action required.
	AbbVie	AbbVie considers the proposed evaluation route to be appropriate.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
Wording	Otsuka Pharmaceuticals UK (company)	The anticipated marketing authorisation is for newly diagnosed AML. Therefore, the draft remit should be reworded to: 'To appraise the clinical and cost effectiveness of decitabine–cedazuridine with venetoclax (DEC-C+VEN) within its marketing authorisation (MA) for treating newly diagnosed acute myeloid leukaemia when intensive induction chemotherapy is unsuitable.'	Thank you for your comment. The remit has been amended in line with the updated marketing authorisation wording.
	Royal College of Pathologists	Yes	Thank you for your comment. No action required.
	AbbVie	The wording of the remit is accurate and reflects the issues of clinical and cost-effectiveness.	Thank you for your comment. No action required.
Timing Issues	Otsuka Pharmaceuticals UK (company)	There is a meaningful clinical need for an oral treatment alternative for patients diagnosed with untreated AML who are ineligible for standard induction chemotherapy (SIC). The frequent in-clinic administration required for current parenteral regimens places a significant burden on frail, elderly patients and their caregivers, and can limit sustained access to disease-modifying treatment. In addition to this, the introduction of an all-oral regimen such as DEC-C+VEN will alleviate operational pressures in NHS day units by reducing the need for repeated in-clinic injections and associated travel. As a result, DEC-C+VEN should be considered a high priority.	Thank you for your comment. NICE has scheduled this topic into its work programme. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11765
	Royal College of Pathologists	Non-urgent as options already available in clinical practice.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
	AbbVie	No comments.	Thank you for your comment. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Otsuka Pharmaceuticals UK (company)	The symptoms and impact of AML on daily life are understated. Whilst the symptoms are correct, the burden of disease has not been identified and is simplified by stating patients feel 'fatigued'. The company would like to emphasise that currently available treatment for AML, regardless of whether intensive or non-intensive, requires patients to visit hospitals for treatment administration for several consecutive days each month, with supportive care to manage the symptom burden including frequent blood transfusions and prophylactic antimicrobials.[1] This imposes a significant burden onto the patient and their caregivers daily life. Additionally, patients accessing non-intensive treatment are characterised by poor general fitness, frailty, and advanced age where these burdens are heightened. The 5-year survival data quoted is misleading as the sentence preceding describes the highest incidence of AML is seen in people aged 75 to 79 years and the data quoted relates to people aged 60 to 69 years where there is a survival rate of 15%. The same source states that for people aged 70 to 79 years the survival rate is much lower at 5% and for people aged 80 to 89 years there is a survival rate of 1%.[2] Additionally, the same source states that people aged 85 to 89 years have the highest incidence of AML diagnoses which, along with the survival rate for this age group, emphasises the severity of the disease and significant disease burden.[3]	Thank you for your comment. The background section of the scope is intended to provide a brief summary of the disease and how it is managed, and is not designed to be exhaustive. The 5 year survival data has been amended and an addition made to indicate that this varies with age. The background section has also been amended to clarify the aim of non-intensive treatment options.

Section	Consultee/ Commentator	Comments [sic]	Action
		Subsequently, the statement that 'the aim of treatment for AML is to cure it' is also misleading as this submission is for a population defined by advanced age that is associated with an increased risk of treatment-related mortality (TRM). The aim of treatment for patients considered unsuitable for intensive induction chemotherapy is to prolong survivorship and reduce symptom burden, but currently is not curative as demonstrated by the survival statistics.[2,4] Finally, the final statement defining non-intensive treatment options for AML is simplified. Whether a patient accesses treatment with ivosidenib (IVO), azacitidine (AZA), or low-dose cytarabine (LDAC) is determined by eligibility considerations that contradict or are outside of the scope of this submission and these are discussed further below in 'Comparators' section. Since the appraisal of TA765, azacitidine in combination with venetoclax (AZA+VEN) is widely considered the standard-of-care (SOC) and first-line treatment choice for patients considered ineligible for intensive induction chemotherapy as confirmed by the British Society for Haematology (BSH), European LeukaemiaNet (ELN) guidelines (2022), and with four UK clinicians.[1,4,5] References: 1.Dennis M, Copland M, Kaur H, et al. Management of older patients with frailty and acute myeloid leukaemia: A British Society for Haematology good practice paper. *British Journal of Haematology*. 2022;199(2):205-221. doi:10.1111/bjh.18369 2.Cancer Research UK (CRUK). Acute myeloid leukaemia (AML): Survival for acute myeloid leukaemia (AML). Accessed 27 January, 2026. https://www.cancerresearchuk.org/about-cancer/acute-myeloid-leukaemia-aml/survival	The treatment options listed in the background section are intended to provide an overview of the available non-intensive treatment options for AML, so these have been retained.

Section	Consultee/ Commentator	Comments [sic]	Action
		3.Cancer Research UK (CRUK). Acute myeloid leukaemia (AML) incidence statistics Accessed 27 January, 2026. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/leukaemia-aml 4.Döhner H, Wei AH, Appelbaum FR, et al. Diagnosis and management of AML in adults: 2022 recommendations from an international expert panel on behalf of the ELN. *Blood*. 2022;140(12):1345-1377. doi:10.1182/blood.2022016867 5.DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and venetoclax in previously untreated acute myeloid leukemia. *N Engl J Med*. 2020;383(7):617-629.	
	Royal College of Pathologists	Background is brief, but accurate and complete.	Thank you for your comment. No action required.
	AbbVie	No comments.	Thank you for your comment. No action required.
Population	Otsuka Pharmaceuticals UK (company)	No, as mentioned above in comment section 1, the MA is for newly diagnosed adult AML patients in whom intensive induction chemotherapy is unsuitable. The wording of the population should reflect this.	Thank you for your comment. The population has been updated in line with the updated marketing authorisation wording.
	Royal College of Pathologists	Yes	Thank you for your comment. No action required.

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	AbbVie	AbbVie considers that the population is appropriately defined.	Thank you for your comment. No action required.
Subgroups	Otsuka Pharmaceuticals UK (company)	No subgroups are considered separately to the target population.	Thank you for your comment. No action required.
	Royal College of Pathologists	No	Thank you for your comment. No action required.
	AbbVie	Treatment availability for azacitidine and venetoclax with low-dose cytarabine (LDAC) in AML is divided according to blast count. As such, the relative clinical and cost-effectiveness for decitabine–cedazuridine with venetoclax has the potential to be different for each sub-group. AbbVie considers the following subgroups relevant for this appraisal: • Azacitidine: Patients with blast counts between 20-30% (with multilineage dysplasia and who are not eligible for HSCT) • Venetoclax with low dose cytarabine: Patients with blast counts over 30%	Thank you for your comment. Following final scope sign off, this topic has been selected for cost comparison and the comparators have been updated to exclude azacitidine monotherapy. Subgroups relating to the proportion of bone marrow blasts and IDH1 R132 mutation status have been added to the scope.

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Comparators	Otsuka Pharmaceuticals UK (company)	Clinician engagement (four consultant haematologists in the UK) confirmed that AZA+VEN is the only clinically appropriate comparator for this submission. AZA+VEN is firmly established as the standard of care in the NHS for adults with newly diagnosed AML who are unfit for intensive chemotherapy, and all clinicians agreed that this regimen is the default first-line treatment for this population. All other options listed are either used exclusively in patients ineligible for VEN (and thus not eligible for DEC-C+VEN), confined to genetically distinct subgroups, or are obsolete as comparators due to displacement by AZA+VEN in routine care. The following comparators are not deemed relevant to this submission: • LDAC-based regimens are now rarely used in NHS practice in unfit AML, a view consistently supported across all interviewed UK clinicians. VEN+AZA became the standard of care following the VIALE-A trial results, which demonstrated superior outcomes compared with LDAC+VEN. As a result, LDAC and LDAC+VEN have been largely displaced in routine practice and are now used only for the small subgroup of patients unable to tolerate HMAs. LDAC-base regimens are therefore not relevant to a submission for DEC-C+VEN, as the same intolerance would apply. • Ivosidenib and azacitidine (IVO+AZA) is recommended for AML patients with an IDH1 R132 mutation, representing 5-10% of AML[6,7]. This submission does not target or explore this genetic subset, and therefore the comparator is not clinically relevant to the population under consideration. The submission for DEC-C+VEN targets mutation-agnostic patients rather than patients eligible for targeted therapy [1]. Leading UK clinicians confirmed that IVO+AZA is used only after genetic confirmation of IDH1-mutation status, with treatment often intentionally delayed to confirm molecular results and ensure patients receive the therapy most	Thank you for your comment. The list of comparators has been amended to remove azacitidine monotherapy and low-dose cytarabine (LDAC) monotherapy. Ivosidenib with azacitidine (for adults with an IDH1 R132 mutation) and venetoclax with low dose cytarabine (for adults with over 30% bone marrow blasts) have been retained as comparators to keep the list of potential comparators inclusive.

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		likely to benefit them. IVO+AZA is not used interchangeably with VEN-based regimens in routine clinical practice. • AZA, for adults not eligible for HSCT and have AML with 20–30% blasts and multilineage dysplasia, is also deemed not relevant to this submission. As described above, HSCT is not classed as intensive induction chemotherapy but instead is a subsequent stage in the treatment of AML reserved for patients in remission. This treatment population is not relevant to this submission. Moreover, AZA monotherapy is also used for patients who cannot receive venetoclax, who are likewise not candidates for DEC-C+VEN. • LDAC monotherapy is reserved for the small proportion of patients who are unsuitable for both venetoclax and HMAs due to frailty, comorbidities, or drug-drug interactions. As DEC-C is an HMA used in combination with venetoclax, this subgroup is not eligible for the technology and therefore not an appropriate comparator. References: 1. Dennis M, Copland M, Kaur H, et al. Management of older patients with frailty and acute myeloid leukaemia: A British Society for Haematology good practice paper. *British Journal of Haematology*. 2022;199(2):205-221. doi:10.1111/bjh.18369 6.Feng JH, Guo XP, Chen YY, Wang ZJ, Cheng YP, Tang YM. Prognostic significance of IDH1 mutations in acute myeloid leukemia: a meta-analysis. *Am J Blood Res*. 2012;2(4):254-64. 7.Schnittger S, Haferlach C, Ulke M, Alpermann T, Kern W, Haferlach T. IDH1 mutations are detected in 6.6% of 1414 AML patients and are associated with intermediate risk karyotype and unfavorable prognosis in adults younger than 60.	

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	Royal College of Pathologists	Yes, these are the standard available treatments in this arena. No treatments have been omitted.	Thank you for your comment. No action required.
Outcomes	Otsuka Pharmaceuticals UK (company)	In clinician interviews, overall survival was described as the most important outcome used in clinical practice. Complete response (CR) and complete response with incomplete count recovery (CRi) rates, as well as time to CR and CR duration, were also considered critical efficacy endpoints. Event-free survival was not collected in ASCERTAIN-V, however it is expected that CR and CRi inherently capture patient response and progression, and are therefore suited to measuring the efficacy of DEC-C+VEN. Progression-free survival was collected as an exploratory endpoint in ASCERTAIN-V, but was not highlighted as a key outcome by clinicians in real-world NHS practice. Reduced hospital days, transfusion support, and resource utilisation data were also considered important by clinicians. Given the oral administration of DEC-C+VEN, cost savings are expected for patients no longer requiring AZA. Given the cost-comparison route, only costs will be considered in the economic model. An indirect treatment comparison (ITC) will be provided in the submission demonstrating comparable efficacy and safety of DEC-C+VEN compared with AZA+VEN. While trial-based utility measures were not collected in ASCERTAIN-V, we will provide qualitative and supportive evidence from clinician interviews on patient-experience benefits such as reduced clinic attendance, avoidance of injection-site pain, and freedom from parenteral therapy.	Thank you for your comment. Following final scope sign off, this topic has been selected for cost comparison. No action required.
	Royal College of Pathologists	Yes, the key outcomes are included, and patient-related outcomes such as health- related quality of life, and transfusion independence are also included.	Thank you for your comment. No action required.

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	AbbVie	AbbVie considers the outcomes listed to be appropriate.	Thank you for your comment. No action required.
Equality	Otsuka Pharmaceuticals UK (company)	In clinician interviews, it was highlighted that patients in remote areas may particularly benefit from an oral regimen to treat their condition. Hospital attendance for 5 to 7 consecutive days when receiving AZA is hugely burdensome for patients with AML, the majority being elderly and frail. It is expected that decitabine-cedazuridine will improve equality in treatment access for patients with untreated AML ineligible for SIC.	Thank you for your comment. This information has been added to the Equality Impact Assessment issued with the final scope.
	Royal College of Pathologists	There are no areas of concern in the draft remit that might impact on equality factors, and I am not aware of any additional evidence that should be sought in this regard.	Thank you for your comment. No action required.
	AbbVie	No comments.	Thank you for your comment. No action required.
Other considerations	Otsuka Pharmaceuticals UK (company)	No additional considerations should be covered.	Thank you for your comment. No action required.
	Royal College of Pathologists	No other considerations	Thank you for your comment. No action required.

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	AbbVie	No comments.	Thank you for your comment. No action required.
Questions for consultation	Otsuka Pharmaceuticals UK (company)	***Where do you consider decitabine–cedazuridine with venetoclax will fit into the existing care pathway for AML?*** DEC-C+VEN will be positioned as a first-line therapy for patients with newly diagnosed AML who are unsuitable for intensive induction chemotherapy, and as an alternative treatment option for patients who would currently be eligible for treatment with AZA+VEN. In current NHS practice, the standard first-line non-intensive option for this population is VEN in combination with a hypomethylating agent (HMA), most commonly AZA. DEC-C provides an oral HMA formulation that can be used in place of parenteral AZA within this established treatment pathway. By offering an oral alternative to AZA within the VEN+HMA regimen, DEC-C+VEN has the potential to reduce the treatment burden associated with frequent in-clinic parenteral administration, while maintaining alignment with current clinical decision-making. Clinician interviews confirmed that DEC-C+VEN would be used in the same patient group who would otherwise receive VEN+AZA, and would not alter the downstream treatment pathway (e.g., eligibility for HSCT or subsequent therapies). ***Have all the relevant comparators been included?*** All relevant comparators have been identified, and relevance of all identified comparators has been discussed in the 'Comparators' section above.	Thank you for your comments. These have been considered when updating the scope. Comments on relevant comparators have been addressed in the response to the "Comparators" section above. Following final scope sign off, this topic has been selected for cost comparison.

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		Can people have intensive induction therapy and then "standard" consolidation therapy rather than intensive chemotherapy at both steps? As mentioned above in comment 2 regarding background information, newly diagnosed AML patients are either considered suitable or unsuitable for intensive chemotherapy based on multiple variables including age, general fitness, polypharmacy, and comorbidities.[8] Patients considered suitable for intensive induction chemotherapy are treated with curative intent, and following CR are moved onto consolidation therapy regimens and considered for HSCT. Patients who access non-intensive treatment are typically not treated with curative intent, and instead the treatment aim is to prolong survivorship and reduce the disease burden.[1] The risk of TRM that characterises a patient as unsuitable for intensive chemotherapy also stands when considering a patient for consolidation chemotherapy with comorbidities and poor general fitness considered negative prognostic factors. Therefore, patients accessing non-intensive treatment will often continue the same regimen of non-intensive treatment as maintenance therapy following CR until disease progression or unacceptable toxicity and are typically not offered consolidation therapy following remission due to high risk of TRM. ***Please select from the following, will decitabine-cedazuridine with venetoclax be:*** ***A. ~~Prescribed in primary care with routine follow-up in primary care~~*** ***B. ~~Prescribed in secondary care with routine follow-up in primary care~~*** ***C. Prescribed in secondary care with routine follow-up in secondary care*** ***D. ~~Other (please give details):~~***	

Section	Consultee/ Commentator	Comments [sic]	Action
		DEC-C+VEN will be prescribed in secondary care with routine follow-up in secondary care. With DEC-C administered orally, administration is anticipated to be quicker and easier compared to current treatment options, with treatment administration can be performed at home when is it deemed appropriate by the treating clinician. ***For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.*** DEC-C+VEN and AZA+VEN are both used in the non-intensive treatment setting for adults with newly diagnosed AML who are unfit for intensive induction chemotherapy. It is expected that decitabine-cedazuridine will be prescribed in the same setting as AZA+VEN (secondary care, hospital-based consultant haematologist). Routine follow-up is also expected to be in the same setting as AZA+VEN as outpatient monitoring appointments. During interviews, clinicians suggested that most patients will require the same monitoring frequency under both regimens to evaluate full blood counts, review transfusion needs, infection surveillance and perform clinical assessments to evaluate tolerance and response to treatment. ***Would decitabine-cedazuridine with venetoclax be a candidate for managed access?*** It is not expected that DEC-C+VEN will require managed access. The evidence package for DEC-C is robust, including Phase 2 combination data with VEN showing consistently favourable OS/CR/CRi and a robust ITC demonstrating comparability in efficacy and safety compared with AZA+VEN. There are no planned additional trials or data cuts that would materially change the evidence base for DEC-C in the next 2–5 years. In addition to this, there is a meaningful unmet need in the target population.	

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		Do you consider that the use of decitabine-cedazuridine with venetoclax can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Given the cost-comparison route for DEC-C+VEN, QALY calculations will not be included in the submission. However, Otsuka has carried out interviews with four leading experts in AML to better understand the value of an oral regimen such as DEC-C+VEN. Clinicians quoted a number of benefits for patients with untreated AML who are ineligible for SIC, such as reduced burden of attending hospital appointments for administration of AZA, which usually lasts 5 to 7 days each month, often scheduled across two weeks, reductions in injection-related toxicities, improved treatment adherence and reduction of strain on NHS day units. A comprehensive report will be provided in the submission dossier detailing the methods and responses of these interviews. In addition to this, the literature documents patient preferences for oral administration in AML and oncology more generally.[9-11] Patients prefer receiving oral treatment if it does not compromise its efficacy and safety, which was also supported by clinicians in the interviews. Additionally, one study reported that 97% AML and MDS patients interviewed agreed their QoL was more important in decision-making than longevity when deciding on treatment options, which highlights a need for alternative treatment options that do not require parenteral administration.[11] The caregiver burden is also documented in the literature, whereby caregivers are burdened by the time spent travelling to and attending appointments. ***Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product***	

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		Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. Real-world evidence (RWE) on the dosing schedule for venetoclax-based regimens for treating AML demonstrate patients experience significant haemato-toxicity and dosing is often interrupted or reduced to allow counts to recover before commencing subsequent treatment cycles, however this is in-line with the SmPC for venetoclax. Articles reporting RWE for the UK cite median days of venetoclax exposure in Cycles 1–2 as 28-days and in Cycles 3–4 as 21-days, with a second study citing median duration for venetoclax exposure in Cycle 1 as 28-days, Cycle 2 as 21-days and Cycles 3 onwards as 14-days.[12,13] Several studies have reported non-inferiority for differing VEN schedules, and a scenario analysis exploring VEN schedules is included within the economic analysis.[14] ***Please provide comments on the appropriateness of appraising this topic through this process***. It is appropriate to consider DEC-C+VEN via the cost-comparison route in line with the NICE Health Technology Evaluation Guidance. No differences in health benefits are expected between DEC-C+VEN compared with AZA+VEN, and it is expected to be positioned in the same place in the treatment pathway. DEC-C+VEN demonstrates comparable or slightly favourable outcomes to AZA+VEN on key endpoints such as OS and CR, as demonstrated by a robust population-adjusted indirect treatment comparison	

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		using individual patient data from ASCERTAIN-V and comparator trial data. The analysis also explored a number of sensitivity analyses to stress-test these conclusions and will be validated with clinicians for inclusion in the evidence submission. Furthermore, the cost-comparison model will include similar costs for DEC-C+VEN compared with AZA+VEN. The clinical evidence for DEC-C+VEN is mature, with no material uncertainty that would require long-term data collection, and its use as an oral alternative to AZA+VEN addresses a meaningful clinical need without raising additional safety concerns. Taken together, these elements meet NICE's criteria for a cost-comparison approach. References: 1. Dennis M, Copland M, Kaur H, et al. Management of older patients with frailty and acute myeloid leukaemia: A British Society for Haematology good practice paper. *British Journal of Haematology*. 2022;199(2):205-221. doi:10.1111/bjh.18369 8. Dennis M, Copland M, Kaur H, et al. Management of older patients with frailty and acute myeloid leukaemia: A British Society for Haematology good practice paper. *Br J Haematol*. Oct 2022;199(2):205-221. doi:10.1111/bjh.18369 9. Delmas A, Batchelder L, Arora I, et al. Exploring preferences of different modes of administration of hypomethylating agent treatments among patients with acute myeloid leukemia. *Front Oncol*. 2023;13:1160966. doi:10.3389/fonc.2023.1160966 10. Eek D, Krohe M, Mazar I, et al. Patient-reported preferences for oral versus intravenous administration for the treatment of cancer: a review of the literature. *Patient Prefer Adherence*. 2016;10:1609-21. doi:10.2147/PPA.S106629	

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		11. Sekeres MA, Stone RM, Zahrieh D, et al. Decision-making and quality of life in older adults with acute myeloid leukemia or advanced myelodysplastic syndrome. *Leukemia*. Apr 2004;18(4):809-16. doi:10.1038/sj.leu.2403289 12. Othman J, Lam HPJ, Leong S, et al. Real-world outcomes of newly diagnosed AML treated with venetoclax and azacitidine or low-dose cytarabine in the UK NHS. *Blood Neoplasia*. Sep 2024;1(3):100017. doi:10.1016/j.bneo.2024.100017 13. O'Nions J, Errico G, Floro L, et al. Results from the Great Britain AML Real World Evidence (ARC) Initiative - a Centre-Based Chart Review Study to Assess Treatment Outcomes of Venetoclax for the Treatment of Acute Myeloid Leukemia. *Blood*. 2024;144(1):7932. doi:10.1182/blood-2024-209926 14. Gangat N, Tefferi A. Venetoclax schedule in AML: 7 vs 14 vs 21 vs 28 days. *Blood Cancer J*. Apr 3 2025;15(1):56. doi:10.1038/s41408-025-01270-4	
	Royal College of Pathologists	- This treatment will fit into the existing care pathway in the same place as alternative regimens, but its selection over other options will depend on its outcome data and tolerability profile in this group of patients. - Intensive induction therapy would only be feasible in patients who are considered 'fit' even if 'standard' consolidation is given, as intensive induction is poorly tolerated by unfit patients with high levels of treatment-related toxicity. - This treatment would be prescribed in secondary care with routine follow-up in secondary care (option C). - This setting is the same for the comparator treatments. - Yes, this treatment would be a suitable candidate for managed access.	Thank you for your comments. These have been considered when updating the scope.

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		- In this patient population, additional focus should be placed on treatments providing patients a reduction in infections, transfusion requirements, or reductions in hospital admission given the shortened life span even when on treatment. Also, given the need to attend a Day Unit for each injection, treatment with 5 vs 7 days of treatment will improve quality of life as well as reduce Day Unit demand. - I am not aware that the treatments in the scope are used outside of their SPC in NHS practice. With my understand of the appraisal process, a cost-comparison process would appear reasonable in this case	
Comments on the provisional stakeholder list	AbbVie	AbbVie have been incorrectly listed as an “Other relevant company”. As AbbVie manufactures venetoclax, a possible relevant comparator, it should be listed as a “Possible comparator company”.	Thank you for your comment. Since the company manufactures venetoclax, which is also part of the treatment combination being appraised, the relevant section on the stakeholder list is under “Other relevant companies” as part of the provisional commentators on the final stakeholder list. No action required.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

Servier