NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Bosutinib for untreated chronic myeloid leukaemia

Final Scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of bosutinib within its marketing authorisation for treating chronic myeloid leukaemia.

Background

Chronic myeloid leukaemia (CML) is characterised by the excessive production of white cell precursors by the bone marrow. Typically, chronic myeloid leukaemia develops and progresses slowly and does not have any symptoms in its early stages. It progresses through 3 phases: the chronic phase, the accelerated phase and the blast crisis phase, with the latter two being grouped together as the advanced phase. The majority of people are diagnosed in the chronic phase, from which they either go through the accelerated phase, or move directly into blast crisis in which the disease transforms into a fatal acute leukaemia.

CML is a rare disease, accounting for less than 1% of all cancer cases[1]. In England in 2014, 631 people were diagnosed with CML[2]. Almost half of all cases of CML are diagnosed in people over 65[3]. A specific chromosomal abnormality known as the 'Philadelphia chromosome' is present in 95% of people with CML[4].

NICE technology appraisal guidance 426 recommends standard dose imatinib, dasatinib and nilotinib as options for untreated, chronic-phase Philadelphia-chromosome-positive CML. NICE technology appraisal guidance 70 also recommends standard dose imatinib for the treatment of people with untreated Philadelphia-chromosome-positive CML who initially present in the accelerated phase or with blast crisis.

The technology

Bosutinib (Bosulif, Pfizer) is a second generation tyrosine kinase inhibitor that inhibits Abl-kinases, including the Bcr-Abl kinsase that promotes CML. It also inhibits the Src family kinases, which have been implicated in driving CML progression. It is administered orally.

Bosutinib does not currently have a marketing authorisation in the UK for untreated chronic myeloid leukaemia. It has been studied in clinical trials in comparison with imatinib, in adults with newly diagnosed chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia.

Bosutinib has a marketing authorisation in the UK for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

Intervention(s)	Bosutinib
Population(s)	Adults with newly diagnosed chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia
Comparators	• Dasatinib • Standard dose imatinib • Nilotinib
Outcomes	The outcome measures to be considered include: • overall survival • progression and/or event-free survival • response rates • 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 patient access schemes for the intervention or comparator 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 and NICE Pathways	**Related Technology Appraisals**: 'Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia' (2017). NICE Technology Appraisal 451. Review date June 2020. 'Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia' (2016). NICE Technology Appraisal 426. Review date December 2019. 'Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia' (2016). NICE Technology Appraisal 425. Review date December 2019. 'Bosutinib for previously treated chronic myeloid leukaemia' (2016). NICE Technology Appraisal 401. Review date August 2019. 'Guidance on the use of imatinib for chronic myeloid leukaemia' (2003). NICE Technology Appraisal 70. Static list. **Related NICE Pathways**: Blood and bone marrow cancers (2017) NICE pathway http://pathways.nice.org.uk/pathways/blood-and-bone-marrow-cancers

Related National Policy	NHS England (2017/18) Manual for prescribed specialised services. Chapters 29 Blood and marrow transplantation services (adults and children) and 105 Specialist cancer services (adults) https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual-2.pdf Department of Health (2014) Improving outcomes: a strategy for cancer fourth annual report https://www.gov.uk/government/publications/the-national-cancer-strategy-4th-annual-report NHS England (2011) Improving outcomes: a strategy for cancer https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213785/dh_123394.pdf Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1, 2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

References

[1] Cancer Research UK Chronic myeloid leukaemia (CML) statistics. Accessed October 2017

[2] Cancer Research UK Chronic myeloid leukaemia (CML) statistics. Accessed October 2017

[3] Cancer Research UK Chronic myeloid leukaemia (CML) statistics. Accessed October 2017

[4] Macmillan Cancer Support Chronic myeloid leukaemia (CML). Access October 2017.