NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia (TA425)

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Summary

NICE has recommended dasatinib as an option for treating imatinib-resistant or intolerant chronic myeloid leukaemia (CML) in adults in line with the criteria set out in the recommendations (see section 1.2).

The company and NHS England have agreed a patient access scheme that makes dasatinib available with a discount (see section 1.3).

Previously nilotinib, with a patient access scheme, was recommended in TA241 and dasatinib was not recommended. This appraisal is a Cancer Drugs Fund partial reconsideration and looks at dasatinib only.

Dasatinib has been available under the Cancer Drugs Fund (CDF) since it was first licensed in the UK to treat chronic or accelerated phase CML that is refractory to, or there is significant intolerance of, imatinib and intolerance of nilotinib. The new guidance results in funding for dasatinib moving into routine commissioning.

Based on the CDF's records of applications, around 120 people with chronic or accelerated phase CML start treatment with dasatinib through the CDF each year. In total, there have been 306 applications since April 2013. It is assumed that all these people were previously treated with imatinib and nilotinib and will continue to be treated with dasatinib in routine commissioning.

Any movement between dasatinib and nilotinib for people currently treated in routine commissioning is unlikely to have a significant resource impact because dasatinib and nilotinib are anticipated to be similarly priced.

It is estimated that around 120 new people will start treatment with dasatinib each year. In addition, there will be around 400 people already being treated through the CDF who will transfer into routine commissioning when funding begins at the time of publication. Dasatinib will not be funded through the CDF from the date of guidance publication on 21 December 2016. Treatment is

expected to continue for an average of 5 years, with 600 people expected to have treatment with dasatinib by 2021/22. Table 1 shows the number of people predicted to be treated over the first 5 years.

Table 1 Number of people predicted to have dasatinib each year in England to 2021/22

	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Total number having dasatinib each year	430	550	600	600	600	600

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1 Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on the Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia in England.

1.2 The guidance states that:

- Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:
    - they cannot have imatinib, or their disease is imatinib-resistant and
    - the companies provide the drugs with the discounts agreed in the relevant patient access schemes.
- High-dose imatinib (that is, 600 mg in the chronic phase or 80 mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant.

1.3 The Department of Health and Bristol-Myers Squibb has agreed that dasatinib will be available to the NHS with a patient access scheme that makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Bristol-Myers Squibb at MG-UKPASADMIN@bms.com.

1.4 This report is supported by a resource impact template that needs the commercial-in-confidence discounted price of dasatinib to be

input into the template to estimate the resource impact. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables in the blue cells.

2 Background and epidemiology of chronic myeloid leukaemia

2.1 CML is characterised by the production of an excessive number of white cell precursors by the bone marrow. It progresses slowly through 3 identifiable phases: the chronic phase, the accelerated phase and the blast phase. There is a specific chromosomal abnormality, commonly known as the Philadelphia chromosome, in 95% of people with CML.

2.2 In 2014, about 600 adults were diagnosed with CML in England (Office for National Statistics, 2016). Table 2 shows details of the population eligible to start treatment with dasatinib each year.

Table 2 Annual number of people with CML eligible for dasatinib in England

Population	Proportion (percentage of previous row)	Number of people
Total population in England aged 18 and over		42,724,917
Incidence of CML [a]	0.001%	619
Number with Philadelphia-chromosome-positive CML [b]	95%	588
Number in the chronic or accelerated phase who have standard-dose imatinib [c]	90%	529
Number intolerant of or whose CML is resistant to standard-dose imatinib [d]	40%	212
Estimated number with CML eligible for second-line treatment each year	-	210

[a] Office for National Statistics: cancer registration statistics, England: first release: 2014. Released on 23 February 2016.
[b] Discussions in the appraisal committee meeting.
[c] From the costing statement for NICE technology appraisal guidance 241.
[d] Final appraisal determination.
Abbreviation: CML, chronic myeloid leukaemia

2.3 Dasatinib has been available through the CDF since it was first licensed in the UK to treat chronic or accelerated phase CML that is refractory to, or there is significant intolerance of, imatinib and intolerance of nilotinib.

2.4 Table 3 shows the number of applications (new people wanting the drug) that NHS England has had for dasatinib for chronic or accelerated phase CML since April 2013.

Table 3 CDF applications received by NHS England for dasatinib for chronic or accelerated phase CML

Year	2013/14	2014/15	2015/16
Number of applications [a]	65	124	117
[a] NHS England. The Cancer Drugs Fund. Data is not available for 2016/17 but it is assumed that there were around 120 applications for treatment.			

2.5 Based on applications in 2015/16, it is assumed that about 120 people will start treatment with dasatinib each year. Because treatment lasts for an average of 5 years, the number of people having dasatinib will accumulate over time (see table 4).

2.6 People who have already started treatment with dasatinib through the CDF will continue treatment in routine commissioning (see table 4).

Table 4 Number of people predicted to have dasatinib each year in England to 2021/22

	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Cumulative number starting treatment with dasatinib after implementation	30	150	270	390	510	600
Number who have started dasatinib treatment in previous years in the CDF	400	400	330	210	90	0
Total number having dasatinib each year	430	550	600	600	600	600

3 Assumptions made

3.1 Table 2 shows the eligible population assumptions used in the resource impact template.

3.2 The resource impact template also makes the following assumptions:

- Any movement between dasatinib and nilotinib for people currently treated in routine commissioning is unlikely to have a significant resource impact because dasatinib and nilotinib are anticipated to be similarly priced.
- Based on clinical opinion, in most people on imatinib treatment, it is anticipated that resistance will develop in the chronic stage because the accelerated phase is quite rare. People who have first-line treatment with imatinib, in whom resistance develops in the chronic phase, will be treated with dasatinib for an average of 5 years (see the resource impact template for more details).
- Administration, monitoring and adverse events costs for dasatinib are already covered by routine commissioning.
- There is insufficient evidence to distinguish between dasatinib and nilotinib in terms of clinical effectiveness.

4 Resource impact

4.1 Table 4 above shows the number of people expected to have treatment with dasatinib each year until 2021/22.

4.2 The list price of dasatinib has a discount that is commercial in confidence. The discounted price can be put into the template to calculate the resource impact of the guidance.

5 Implications for commissioners

5.1 Dasatinib will be available through routine commissioning and there will be a resource impact for NHS England specialised commissioning. Dasatinib will no longer be funded through the CDF from guidance publication on 21 December 2016.

5.2 Dasatinib falls within the programme budgeting category 2I: Cancers & Tumours – Haematological.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on the dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia and should be read in conjunction with it. See terms and conditions on the NICE website.