NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:

Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation (TA429)

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Summary

NICE has recommended ibrutinib alone as an option for treating chronic lymphocytic leukaemia (CLL) in adults who have had at least 1 prior therapy or who have a 17p deletion or TP53 mutation, and in whom chemo-immunotherapy is unsuitable.

Other treatment options are idelalisib plus rituximab or best supportive care for people who cannot take these drugs.

Ibrutinib is already funded by the NHS through the Cancer Drugs Fund (CDF) for people with relapsed or refractory CLL. Ibrutinib will now be available through routine commissioning, and there will be a resource impact for specialised commissioning.

The guidance will increase the number of people who have ibrutinib because it expands the indication to include people with untreated CLL who have a 17p deletion or TP53 mutation. These people currently have idelalisib plus rituximab based on the NICE guidance on idelalisib for treating chronic lymphocytic leukaemia.

Around 1,000 adults with previously treated CLL and untreated CLL with 17p deletion or TP53 mutation are estimated to be eligible for treatment with ibrutinib.

It is estimated that about 700 adults will have treatment with ibrutinib under this guidance from year 2017/18 onwards. The estimated numbers of adults in England who will have ibrutinib each year based on the uptake in the resource impact assumptions are shown in table 1.

Table 1 Estimated numbers of adults who will have ibrutinib in England

Year	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**
Number of people predicted to have ibrutinib each year	0	700	700	700	700

This report is supported by a local resource impact template because the list price of ibrutinib has a discount that is commercial in confidence. The discounted price of ibrutinib can be put into the template and other variables may be amended.

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 technology appraisal guidance on ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation in England.

1.2 The guidance states that:

- Ibrutinib is recommended within its marketing authorisation as an option for treating CLL in adults:
  - who have had at least 1 prior therapy or
  - who have a 17p deletion or TP53 mutation, and chemo-immunotherapy is unsuitable
  - only when the company provides ibrutinib with the discount agreed in the patient access scheme.

1.3 The Department of Health and Janssen have agreed that ibrutinib will be available to the NHS with a patient access scheme, which 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 Janssen on 01494 567 400 or at janssenukcustomerservices@its.jnj.com.

1.4 This report is supported by a resource impact template. 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.

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

2 Background and epidemiology of chronic lymphocytic leukaemia

2.1 CLL is type of cancer of lymphocytes (white blood cells). It causes anaemia, swollen lymph nodes, spleen enlargement, weight loss, persistent tiredness and increased susceptibility to infection. It is an incurable disease and is extremely variable in its clinical course.

2.2 There are limited treatment options for adults with untreated CLL associated with 17p deletion or TP53 mutation for whom chemo-immunotherapy is not suitable.

2.3 There were about 3,100 adults newly diagnosed with CLL in England in 2014 (Office for National Statistics, 2016).

2.4 Table 2 shows details of the population eligible for ibrutinib in England.

Table 2 Number of people with CLL eligible for treatment with ibrutinib in England

Population	Percentage (%)	Number of people
Total adult population in England		42,724,917
Incidence of CLL[a]	0.01	3,100
People with CLL without 17p or TP53 mutation[b]	93	2,900
People with CLL without 17p or TP53 mutation who have first-line treatment[c]	67	1,900
People with CLL without 17p or TP53 mutation whose disease has not responded to first-line treatment and which is eligible for second-line treatment[d]	60	1,200
People with CLL without 17p or TP53 mutation whose disease has not responded to first-line treatment and which is eligible for second-line treatment, including ibrutinib[c]	75	870
People with CLL who have a 17p deletion or TP53 mutation at diagnosis **(7% x 3,100)**[b]	7	220
People with CLL who have a 17p deletion or TP53 mutation at diagnosis whose disease has not responded to first-line treatment and which is eligible for ibrutinib[c]	80	170
People who have had at least 1 prior therapy or who have a 17p deletion or TP53 mutation and for whom chemo-immunotherapy is unsuitable with CLL that is eligible for ibrutinib **(870 + 170)**		1,040
People estimated to have ibrutinib each year from year 2017/18[e]	67	700

a. Cancer Registration Statistics, England, 2014. Table 6: Registrations of newly diagnosed cases of cancer: ICD 10 Code: C91.1 Chronic lymphocytic leukaemia.

b. Dohner H, Stilgenbauer S, Benner A et al. Genomic aberrations and survival in chronic lymphocytic leukemia. N Engl J Med. 2000; 343(26):1910-6.

c. Based on the company consultation comments

d. Clinical expert opinion. See pathway worksheet for population assumptions. This is based on the resource impact template for the NICE guidance on idelalisib for treating chronic lymphocytic leukaemia

e. NHS England estimate.

Abbreviation: CLL, chronic lymphocytic leukaemia.

2.5 Therefore, it is estimated that about 1,000 people have CLL that is eligible for treatment with ibrutinib each year.

2.6 From year 2017/18, it is estimated that around 700 people will have treatment with ibrutinib each year once uptake has reached 67%.

3 Assumptions made

3.1 The resource impact template makes the following assumptions:

- Current and future uptake estimates of ibrutinib are based on data provided by NHS England.

4 Resource impact

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

4.2 The current treatment and future uptake figure assumptions are based on NHS England consultation comments. Table 3 shows the number of people that are predicted to have ibrutinib by financial year. Activity is not anticipated to change year on year because the majority of activity is a transfer from the CDF.

Table 3 Estimated numbers of adults who will have ibrutinib in England using NICE assumptions

	2016/17	2017/18	2018/19	2019/20	2020/21
Number of people predicted to have ibrutinib each year	0	700	700	700	700

5 Savings and benefits

5.1 The committee concluded that ibrutinib offered a more preferable toxicity profile, and was likely to offer progression-free and overall survival benefits compared with idelalisib plus rituximab, but was mindful that the extent of this benefit was uncertain.

5.2 The committee also concluded that ibrutinib was likely to be more effective compared with best supportive care than when compared with idelalisib plus rituximab.

5.3 The committee heard from the patient and clinical experts that ibrutinib is an important new technology in the treatment of CLL, and they appreciate the benefits to an oral method of administration.

6 Other considerations

6.1 The model assumes 8 cycles of idelalisib plus rituximab as rituximab is given for a maximum of 8 cycles. After 8 cycles rituximab stops and idelalisib continues until progression.

6.2 Ibrutinib is administered orally at a daily dose of 420 mg until disease progression or intolerance.

7 Implications for commissioners

7.1 The technology will be available through routine commissioning, and there will be a resource impact for specialised commissioning. The technology was previously funded from the Cancer Drugs Fund (CDF). Ibrutinib will not be funded from the CDF from 90 days after the publication of the guidance on 25/01/2017.

7.2 Ibrutinib for treating CLL falls within the programme budgeting category 02I cancer, haematological.

8 About this resource impact report

This resource impact report accompanies the NICE guidance on Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation and should be read in conjunction with it. See terms and conditions on the NICE website.