NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Voclosporin with mycophenolate mofetil for treating lupus nephritis (TA882)

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Summary

NICE has recommended voclosporin with mycophenolate mofetil for treating active class 3 to 5 (including mixed class 3 and 5, and 4 and 5) lupus nephritis in adults. It is only recommended if the company provides it according to the commercial arrangement (see section 2 of the guidance).

We estimate that:

- 12,800 people with lupus nephritis are eligible for treatment with voclosporin with mycophenolate mofetil (MMF), after allowing for population growth.
- In year 2027/28, once the market share of voclosporin with MMF has reached 10%, around 520 people will start treatment and around 760 people will continue treatment from previous years. This is shown in table 1.
- From the trial data, the average time people receive treatment is 36 months.
- Where uptake of voclosporin with MMF displaces treatments delivered by intravenous infusion (IV) there are potential cost savings and capacity benefits. The annual capacity benefits are shown in table 2.

Table 1 Estimated number of people in England receiving voclosporin with MMF

	2023/24	2024/25	2025/26	2026/27	2027/28
Market share for voclosporin with MMF (%)	2	4	6	8	10
People starting voclosporin with MMF each year	250	250	260	510	520
People continuing voclosporin with MMF from previous years	0	250	500	510	760
Total	**250**	**500**	**760**	**1,020**	**1,280**

Table 2 Estimated capacity released from reduced appointments needed at IV services in England

	2023/24	2024/25	2025/26	2026/27	2027/28
Appointments released at IV infusion services	400	600	860	1,000	1,000

This report is supported by a local resource impact template because the list price of voclosporin has a discount that is commercial in confidence. The discounted price of voclosporin 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 Voclosporin

1.1 NICE has recommended voclosporin with mycophenolate mofetil for treating active class 3 to 5 (including mixed class 3 and 5, and 4 and 5) lupus nephritis in adults. It is only recommended if the company provides it according to the commercial arrangement (see section 2 of the guidance)

1.2 Current treatments for lupus nephritis are used to either induce or maintain remission. All treatments include some use of corticosteroids. The immunosuppressives used to induce remission include methylprednisolone (steroid) with mycophenolate mofetil, low- and high-dose cyclophosphamide, rituximab with mycophenolate mofetil, and tacrolimus with or without mycophenolate mofetil. Maintenance treatments include mycophenolate mofetil, azathioprine and tacrolimus monotherapy.

1.3 Clinical experts and the Innovative Medicines Fund clinical lead explained that voclosporin would be used to induce remission and not as a maintenance treatment. Patient and clinical experts explained how current treatments have significant adverse effects. These side effects can cause other conditions that need separate treatment. They also severely impact quality of life and in some cases may affect adherence to dosing regimens. Voclosporin is an effective treatment with manageable side effects; it is part of an oral tablet regimen which can be taken by people at home. This will have capacity benefits for the NHS where it replaces current IV options.

2 Resource impact of the guidance

2.1 We estimate that:

- 12,800 people with lupus nephritis are eligible for treatment with voclosporin with mycophenolate mofetil (MMF), after allowing for population growth.

- In year 2027/28, once the market share of voclosporin with MMF has reached 10%, around 520 people will start treatment and around 760 people will continue treatment from previous years. This is shown in table 3.
- From the trial data, the average time people receive treatment is 36 months.
- Where uptake of voclosporin with MMF displaces treatments delivered by intravenous infusion (IV) there are potential cost savings and capacity benefits. The annual capacity benefits are shown in table 4.

2.2 The current treatment and future uptake figure assumptions are based on clinical expert opinion and are shown in the resource impact template. Table 3 shows the number of people in England who are estimated to receive voclosporin by financial year. Table 4 shows potential capacity benefits at IV infusion services.

Table 3 Estimated number of people receiving voclosporin using NICE assumptions

	2023/24	2024/25	2025/26	2026/27	2027/28
Cumulative uptake rate for voclosporin with MMF (%)	2	4	6	8	10
People starting voclosporin with MMF each year	250	250	260	510	520
People continuing voclosporin with MMF from previous years		250	500	510	760
Total	**250**	**500**	**760**	**1,020**	**1,280**

Table 4 Estimated capacity released from reduced appointments needed at IV services in England

	2023/24	2024/25	2025/26	2026/27	2027/28
Appointments released at IV infusion services	400	600	860	1,000	1,000

2.3 This report is supported by a local resource impact template. Voclosporin has a commercial arrangement (simple discount patient access scheme). This makes voclosporin available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount. The discounted price of voclosporin can be put into the template and other variables may be amended.

3 Implications for commissioners

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

3.2 Voclosporin falls within the programme budgeting category 15 'Problems of the Musculo Skeletal system'.

4 How we estimated the resource impact

The population

4.1 In England and Wales, systemic lupus erythematosus (SLE) is estimated to be prevalent in around 60,000 people (Reece et al 2016) adjusted to the England population (92%), this is around 55,000 people. The British Society for Rheumatology guidelines state that about one-third of SLE patients in the UK develop lupus nephritis.

Table 5 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total population		54,786,327
Adult population (after adjusting for population growth)		46,263,200
Prevalence of systemic lupus erythematosus (SLE) in England[1]	0.12%	55,000
Proportion of people who develop lupus nephritis (LN)[2]	33.33%	18,300
Proportion of people who have active class 3 to 5 (including mixed class 3 and 5, and 4 and 5) LN[3]	70%	12,800
Total number of people eligible for treatment with voclosporin with MMF		12,800
Total number of people estimated to receive voclosporin with MMF each year from year 2027/28	10	1,280

[1] Reece et al 2016

[2] British Society for Rheumatology

[3] Mahajan A, Amelio J, Gairy K, et al. Systemic lupus erythematosus, lupus nephritis and end-stage renal disease: a pragmatic review mapping disease severity and progression. Lupus 2020; 29(9): 1011-20

Assumptions

4.2 The resource impact template assumes that:

- The average time people receive treatment is 36 months, based on the AURORA 2 study (company submission).
- Voclosporin with MMF are oral capsules therefore no administration costs are associated with the treatment (per company submission).
- The careful monitoring of renal function needed with voclosporin is included within routine monitoring for lupus nephritis (see paragraph 3.9 of the guidance), therefore no additional monitoring costs have been assumed.

- Comparator treatments have been in use for some time, therefore the population receiving these treatments each year is assumed to remain constant (i.e. people starting / continuing / discontinuing are at similar rates).

- The use of corticosteroids in current and future practice varies only by the regimen taken (this includes voclosporin with MMF – see paragraphs 3.2 & 3.3 of the guidance), this is not anticipated to change significantly as a result of implementing the guidance.

- The 2022/23 tariff SB14Z 'Deliver complex chemotherapy including prolonged infusional treatment at first attendance' - £483 can be used a proxy for estimating the administration cost of treatments administered via IV infusion in the absence of a specific tariff for lupus nephritis IV treatments.

Table 6 Assumptions made on current and future practice.

People eligible for voclosporin with MMF		
Current Practice	**Future practice (year 5)**	**Rationale**
0% of people receive voclosporin with MMF	**10%** of people receive voclosporin with MMF	Estimated market share (can be amended locally)
65% of people receive MMF alone	**58%** of people receive MMF alone	Estimated market share (can be amended locally)
3% of people receive low-dose cyclophosphamide (IV)	**3%** of people receive low-dose cyclophosphamide (IV)	Estimated market share (can be amended locally)
3% of people receive high-dose cyclophosphamide (IV)	**3%** of people receive high-dose cyclophosphamide (IV)	Estimated market share (can be amended locally)
15% of people receive azathioprine	**13%** of people receive azathioprine	Estimated market share (can be amended locally)

12% of people receive rituximab (IV) with MMF	**11%** of people receive rituximab (IV) with MMF	Estimated market share (can be amended locally)
1% of people receive tacrolimus and MMF	**1%** of people receive tacrolimus and MMF	Estimated market share (can be amended locally)
1% of people receive tacrolimus monotherapy	**1%** of people receive tacrolimus monotherapy	Estimated market share (can be amended locally)
Total 100%	**Total 100%**	
(IV) = Intravenous infusion. IV treatments for lupus nephritis require hospital attendance.		

About this resource impact report

This resource impact report accompanies the NICE guidance on Voclosporin with mycophenolate mofetil for treating lupus nephritis (TA882) and should be read with it.