NICE National Institute for Health and Care Excellence

Resource impact summary report

Resource impact
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Resource impact summary report

This summary report is based on the NICE assumptions used in the resource impact template. Users can amend the 'Population and treatments' and 'Unit costs' worksheets in the template to reflect local data and assumptions.

Guidance recommendations

See NICE's recommendations on rozanolixizumab for treating antibody-positive generalised myasthenia gravis.

Financial and capacity resource impact

The company has a commercial arrangement (simple discount patient access scheme). This makes rozanolixizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

Users can input the confidential price of rozanolixizumab and amend other variables in the resource impact template.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

Clinical trial evidence suggests that rozanolixizumab plus standard treatment reduces symptoms and improves people's ability to carry out their normal activities compared with standard treatment alone. But it is uncertain if this improvement lasts in the longer term. Indirect comparisons suggest that rozanolixizumab works better than intravenous immunoglobulin (IVIg) or plasma exchange (PLEX), but the extent of the benefit is uncertain.

Rozanolixizumab is administered as a short subcutaneous infusion given weekly, for 6 weeks, equivalent to 1 treatment cycle. As a once-weekly subcutaneous infusion, rozanolixizumab may avoid the need for frequent IV administration and procedures while minimising the treatment burden to patients.

Subsequent treatment cycles of rozanolixizumab should be administered according to clinical evaluation. The frequency of treatment cycles may vary by patient. In the clinical development programme, most patients had treatment-free intervals of 4 to 13 weeks between cycles.

Clinical experts estimate 4 cycles for rozanolixizumab per year which incorporates treatment-free intervals. Users can amend the number of cycles to reflect local assumptions.

Administration of rozanolixizumab is assumed to require 60 minutes of nurse time on treatment initiation, then reduced to 30 minutes in subsequent model cycles. After the first cycle, rozanolixizumab can be self-administered at home. Users can update the proportion of cycles prescribed in secondary care and at home in the resource impact template.

The annual drug cost for rozanolixizumab is based on a weighted average of doses, reflecting the patient weight distribution observed in the MycarinG clinical trial.

In the resource impact template, the number of GP, specialist appointments and adverse events are shown for controlled and uncontrolled status and are based on the health economics. These are then weighted based on the proportion of people in each state.

Rozanolixizumab may reduce the risk of myasthenic crisis and exacerbations in patients with uncontrolled disease.

SB12Z (deliver simple parenteral chemotherapy at first attendance) is used as a proxy for the administration costs for rozanolixizumab, and SB14Z (deliver complex chemotherapy, including prolonged infusional treatment, at first attendance) is used as a proxy for the administration costs for IVIg.

Plasma exchange includes the procedure costs using HRG SA14Z (plasma exchanges, 2 to 9) per cycle and administrations costs using SA44A (single plasma exchange or other intravenous blood transfusion 19 years and over) per session.

Users can update the number of administration, appointment and other variables in the resource impact template to reflect local practice.

Eligible population for rozanolixizumab

For this evaluation, the company asked for rozanolixizumab to be considered for generalised myasthenia gravis if:

- it is classified as Myasthenia Gravis Foundation of America (MGFA) class 2 to 4a
- it is uncontrolled after 2 or more treatments, excluding acetylcholinesterase inhibitors, and
- IVIg or PLEX is being administered or considered.

Some people with generalised myasthenia gravis have intravenous immunoglobulin or plasma exchange, or both, and have to stop treatment because of side effects or because it did not work well enough. This group of people is included in the recommendation.

The following assumptions have been used to calculate the eligible population:

- the prevalence of myasthenia gravis is estimated to be 0.0337% of the adult population (see Carey et al. 2021)
- 85% of adults with myasthenia gravis are classified as generalised (see Jackson et al. 2022)
- the NHS England submission estimated that 85% test positive for anti-AChR or MuSK antibodies
- of adults with generalised myasthenia gravis that test positive for anti-AChR or MuSK antibodies, 93% are classified as MGFA class 2 to 4a (see Kalita et al. 2025)
- of those, clinical experts estimate that 12.5% have refractory disease (after receiving steroids or immunosuppression).

Access to IVIg and PLEX is highly variable across the NHS. Update current and future market share in the resource impact template for each treatment option to reflect local assumptions.

Treatment options for the eligible population

Standard treatment for generalised myasthenia gravis in adults who test positive for

anti-AChR or anti-MuSK antibodies includes:

- surgery
- acetylcholinesterase inhibitors
- corticosteroids
- non-steroidal immunosuppressants.

For some people whose condition does not improve with standard treatment, IVIg or PLEX may be added. But access to IVIg or PLEX varies, and they are not suitable for everyone. So, people who cannot have them continue to try standard treatments. Rozanolixizumab would be used as an add-on to corticosteroids or non-steroidal immunosuppressants.

For more information about the treatments, such as dose and average treatment duration, see the resource impact template.

Key information

Table 1 Key information

Time from publication to routine commissioning funding	90 days
Programme budgeting category	07X Neurological, Neurological
Commissioner	NHS England
Provider	Primary care and NHS hospital trusts
Pathway position	Generalised myasthenia gravis

About this resource impact summary report

This resource impact summary report accompanies the NICE technology appraisal guidance on rozanolixizumab for treating antibody-positive generalised myasthenia gravis and should be read with it.

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