COMMISSIONING IMMUNOGLOBULIN

Advice to commissioners and commissioning bodies

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Comment on:
SECOND EDITION UPDATE

Clinical Guidelines for Immunoglobulin Use

October 2011

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1. Introduction

In May 2009, the National Specialised Commissioning Group published version two of the Model Commissioning Policy for immunoglobulin, which provides the framework for the provision and supply of intravenous and subcutaneous immunoglobulin (IVIG/SCIG) to those patients with the highest priority (1,2). The policy provides a clear statement of the commissioning position and the decision-making process for each category of treatment.

This document has been written by commissioners with experience of immunoglobulin in response to the recent publication by the Department of Health of the Second Edition Update to the Clinical Guidelines for Immunoglobulin Use (3) to inform commissioners and commissioning bodies about the update and its implications for commissioning practice.

The intention remains that funding for immunoglobulin will be tied to appropriate prescribing as recorded in the National Immunoglobulin Database. As the new NHS commissioning arrangements become clearer in 2012/13, the database will be revised and refined to ensure it is fit for purpose to perform its role in this important task.

2. Selection criteria for immunoglobulin use

The Clinical Guidelines for Immunoglobulin Use Second Edition (4) frequently referred to 'selected patients' within the recommendations, but did not provide explicit selection criteria for the appropriate use of immunoglobulin. This vagueness resulted in wide and varied interpretation both between and within individual Trusts. The Second Edition Update attempts to address this issue and now provides criteria that are to be fulfilled if immunoglobulin is to be used, including particular disease characteristics, disease severity and any requirement for other treatments to have been demonstrably unsuccessful before immunoglobulin is considered (3).

From a commissioner's perspective, effective Immunoglobulin Assessment Panels (IAPs) are important to monitor adherence to these new selection criteria in routine clinical practice. IAPs are provider, rather than commissioner, based – as described in The Demand Management Plan for Immunoglobulin Use (5). Commissioners should be represented on IAPs, but the degree to which this happens in practice varies. IAPs with strong commissioner input can be robust in ensuring compliance with the selection criteria. For those IAPs without a commissioner, other approaches may be needed to encourage compliance. This could include using the contractual arrangements with Trusts to drive appropriate prescribing. An example is the East Midlands Specialised Commissioning Group, which has incorporated a requirement for National Immunoglobulin Database entry as a condition for payment. Bespoke immunoglobulin prescribing reports are generated from the commissioners' portal on the database, which document the total volume and cost of each product prescribed per Trust. These data are used to calculate the 'spend' entered onto the database. Payments are withheld from the Trust if the spend and the actual volume used do not correlate.

In addition, changes to the National Immunoglobulin Database are being introduced to help track and automate as far as possible compliance with the Clinical Guidelines. As specified in the Second Edition Update, the colour-coded prioritisation category, as used in the Demand Management Programme (Red, Blue and Grey), will now be automatically assigned by the National Immunoglobulin Database (3). This will prevent the assignment of incorrect colour codes, which occurred frequently under the previous system (6). Enhanced commissioner reporting tools are being integrated into the National Immunoglobulin Database to facilitate monitoring of prescribing to ensure fulfilment of these criteria.

3. Outcome criteria for immunoglobulin use

Efficacy and safety monitoring are important issues when prescribing an expensive blood product such as immunoglobulin. Although recommended in the Clinical Guidelines, efficacy tracking was left to the individual hospitals to complete; however, compliance has been extremely poor (6). The Second Edition Update now requires efficacy outcomes to be measured in all indications (except those patients with primary immunodeficiency) and the findings to be recorded in the National Immunoglobulin Database.

The update specifies the outcome(s) measures, but not the degree in improvement of outcome(s) required to constitute treatment success. In some treatment indications it is challenging to define the exact change in clinical condition that constitutes treatment success. The National Immunoglobulin Database Steering Committee are continuing to review and refine these outcomes to provide defined 'treatment success' measures.

For transplantation indications, a series of clinical measures were specified by the British Transplantation Society to record in the database. Treatment success will be reviewed and analysed after one year, and a further decision taken then on the future status of these indications based on the review findings.

Regarding stopping rules for immunoglobulin treatment, for most diseases the treatment duration is short term (<3 months). The update specifies that the treatment episode ends at 3 months; treatment re-initiation will be regarded as a new treatment episode, based on a new IAP decision. For long-term treatment, annual reviews are obligatory and efficacy outcomes must be recorded. A treatment episode will automatically terminate at 12 months (except for primary immunodeficiencies). Development of the database by The National Immunoglobulin Database Steering Committee is continuing and new features will include automated tools to support implementation of the stopping rules at 3 and 12 months. Further data entry will only be possible once a new IAP decision has been recorded.

4. Cost effectiveness and affordability of immunoglobulin

Ensuring immunoglobulin prescribing is consistent with the evidence-base and restricted to those patients for whom there are no alternative treatments and for those most likely to benefit is the central aim of the clinical guidelines. From a commissioners' viewpoint, cost-effectiveness and affordability are important criteria. NICE uses a cost effectiveness threshold of £20-30,000 per quality-adjusted life year gained to establish efficient use of NHS resources. It is the responsibility of commissioners and the IAPs to consider cost-effective use of immunoglobulin on a case by case basis, particularly in the present financial context.

As a result, those commissioning immunoglobulin are advised to closely scrutinise large-volume using indications such as CIDP to ensure that the strict selection criteria specified in the guidelines are adhered to and that the outcomes specified are appropriate and offer value for money. In immune thrombocytopenia purpura (ITP), the Second Edition Update makes clear that immunoglobulin should only be used as short-term treatment for specific circumstances in newly diagnosed (acute) or persistent (3 to 12 months duration) ITP (see update p.37 for details)(3). Patients with ongoing ITP beyond 12 months (chronic ITP) should not normally be treated with long-term immunoglobulin as there are alternative approaches (see update p.38). To reflect this, immunoglobulin in chronic ITP is now a Grey indication and long-term use in patients who have had ITP over 12 months will require authorisation by the PCT/commissioner, as well as approval from the IAP. However, for patients with chronic ITP who experience a sudden acute bleeding event or require surgery, the episode should be recorded in the database as Red and regarded as a new, acute episode of care.

All immunoglobulin products are considered generic and therefore the commissioners insist that, when prescribers begin treatment on a new patient, the product with the lowest acquisition cost should be used unless compelling reasons for using an alternative have been specified as part of the IAP's approval.

Commissioners should enforce the guideline recommendation that for patients on long-term immunomodulatory doses, attempts are made to reduce the dose, by increasing the dosing interval or by using reduced dose, or both, and, that for patients with a high BMI, adjusted-body-weight dosing is used. As the recommended doses have been largely empirical, there should be strong consideration given to this dose-reduction approach in clinical practice. The National Database captures dosing and this is an obvious area for future data review and analysis. This should reduce costs and help conserve supplies of immunoglobulin without compromising individual patient outcomes.

5. Conclusion

Commissioners of immunoglobulin will welcome the publication of The Second Edition Update to the Clinical Guidelines for Immunoglobulin Use (3). In particular, increased clarity regarding patient selection criteria and the need for prescribers to report clinical outcome after treatment are strongly supported.

IAPs play a key role in ensuring these guidelines are implemented in clinical practice. The National Immunoglobulin Database Steering Committee are continuing to meet and will drive the technical changes required. When completed, the enhanced commissioner reporting tools integrated into the National Immunoglobulin Database will facilitate: monitoring of prescribing patterns, identification of individual cases which do not meet the selection criteria, and tracking of cases that do not have (appropriate) outcome measures. In the future these will be highlighted to commissioners through automated email alerts and automatic stopping rules through database locking to prevent inappropriate unsanctioned use. This will make it possible to link payment for immunoglobulin to appropriate prescribing as recorded in the National Immunoglobulin Database.

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