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An analysis of AAN's evidence-based guideline for IVIg use in neurologic disorders

Provider impact and payer perspectives

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Summary

Health insurers look for reliable, published evidence such as evidence-based guidelines put forth by medical specialty societies to craft their coverage policies. These guidelines generate both beneficial and controversial consequences on policies. Coverage policies aim to address the most typical clinical presentations. The American Academy of Neurology guideline for IV immunoglobulin strengthens the case for coverage when it is used to treat Guillain-Barré syndrome and chronic inflammatory demyelinating polyradiculoneuropathy. The guideline is less likely to strengthen coverage for several other diagnoses with lower levels of evidence. The responsibility to clarify specific situations when patient need falls outside of what is considered to be routine evaluation or treatment rests heavily on the physician. Advice on appealing an unfavorable coverage decision is also provided to the reader.

Insurers look for reliable, published evidence to craft their coverage policy. Policies are developed mainly to define conditions that are reasonable and necessary for assuring payment. Policies succeed by addressing the most typical clinical presentations. Atypical situations often fall outside the purview of policies, requiring separate and individual consideration for coverage.

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Evidence-based guidelines generate both beneficial and controversial consequences on coverage policy. Positive coverage decisions follow high-quality evidence. Lower-quality and insufficient evidence may result in either denial or restriction of existing coverage. The American Academy of Neurology (AAN) clinical practice guideline (CPG) on IV immunoglobulin (IVIg)¹ could have beneficial, but also mixed, consequences:

- The CPG will strengthen the case both for coverage of and appeals against denials of IVIg when it is used in treating Guillain-Barré syndrome (GBS; also known as acute inflammatory demyelinating polyneuropathy [AIDP]) and chronic inflammatory demyelinating polyneuropathy (CIDP).
- The CPG is less likely to be helpful when IVIg is used by neurologists for diagnoses with lower levels of evidence. As the guideline shows, the diagnostic group covered in the guideline is a large one; there are varying degrees of confidence in its evidence base. It includes use of IVIg in children with GBS, exacerbations of myasthenia gravis (MG), multifocal motor neuropathy (MMN), and myositides. Providers, as they weigh their treatment options, should be aware of the potential for a curtailing impact of the CPG. As outlined at the end of this analysis, there are steps to take to mitigate the potential impact.
- The CPG contains no assessment of evidence for some diagnoses that are already covered by a few payers. Those who cover MS, refractory epilepsy, or stiff-person syndrome may consider revising their current coverage status, even though reversal of established practices is not easy.²
- The CPG acknowledges “overtreatment” as an issue for awareness and also allows for “expert” opinions in some of its conclusions. When payers are reviewing appeals against continued or frequent treatments, the terms “overtreatment” and “expert” opinions may create ambiguity in interpretation. Citing overtreatment as an issue, some payers may put in limits, appropriately or otherwise, to the frequency of IVIg administration. Other payers may seek expert reviews, instead, before making denial or continued coverage decisions. The choice of an expert or the acceptance of their recommendations is left to the payer staff. Thus, subjectivity enters the decision-making process.
- IVIg is used in a large number of non-neurologic conditions such as immune deficiency syndromes and transplant services. Payers are conversant with the evidence base, controversies for each usage, and the settings in which the treatments are given. Payers have access to utilization and trending data from large national and local groups of users. They are aware of cost-effectiveness data of many therapies, including IVIg, even with its inherent uncertainties.³ Payers may be unfamiliar, however, with diagnostic nuances and variant terminologies used by neurologists. This is one area where dialogue and education by neurologists to their payer medical staff is critically important.

Diagnosis-specific remarks

Guillain-Barré syndrome In GBS, with appropriate coupling of procedure and diagnostic codes, there should be no impediment to coverage of IVIg in a majority of cases.

The CPG conclusion that “IVIg is as efficacious as plasma exchange for treating GBS in adults” coupled with an earlier AAN guideline statement, “Immunoglobulin IV (IVIg) is an alternative treatment used in patients with AIDP/GBS. There is insufficient evidence to demonstrate the superiority of one treatment over the other,” is helpful because alternatives should be viewed as equivalent options until evidence shows otherwise. Thus, the use of IVIg becomes justifiable, and harder to challenge, in instances where plasma exchange is unavailable or unsuitable for various reasons. In fact, some payers already recognize this and allow use of IVIg when plasma exchange is not used for various reasons such as “difficult venous access.”⁴

Chronic inflammatory demyelinating polyneuropathy Unlike AIDP, CIDP requires attention to clear delineation of diagnostic criteria. Payers’ requirements for establishing a diagnosis of CIDP vary from general descriptive statements to very stringent criteria.⁴ These



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criteria are applicable to any CIDP treatment such as plasma exchange or IVIg. In making a diagnosis of CIDP, physicians must adhere to a majority, if not all, of the clinical and laboratory criteria set forth by specialty societies such as the AAN or European Federation of Neurology.^{5,6} Otherwise, payers could consider IVIg, or “pheresis” for that matter, unproven in patients who do not fulfill the specific diagnostic criteria.

When treatment is initiated, it is necessary to document progress meticulously. If there is initial improvement, and continued treatment is necessary, quantitative assessment to monitor the progress is required. Reliance on surrogates such as electrophysiology or spinal fluid/serum chemistry is useful only when also coupled with clinical assessments. Some payers tend toward being prescriptive about the frequency or duration of treatments, others rely on available published evidence and consensus, and still others may consider IVIg as not cost-effective in comparison with corticosteroids.³ These payers will ask for medical records, seek an external review of records, and monitor utilization prospectively in select instances. These types of prepay or postpay reviews are the mechanisms available to detect, monitor, or temper excessive use.

It is unlikely that there will be a concerted impediment to provision of coverage in clearly established instances of CIDP. The CPG conclusion, “IVIg is effective for the long-term treatment of CIDP,” is certainly helpful in obtaining coverage for the treatment. It is the duration, frequency, and dosage of treatment that are likely to be sources of denial of payment, review of coverage, or payer-provider discussions and dialogues.

Myasthenia gravis Coverage difficulties are generally unlikely in MG when moderate to severe exacerbations occur and are clearly documented. The AAN’s CPG calls for “further studies” and maintains that IVIg “is probably effective” in MG. This balanced position could encourage denial and review when IVIg is used under less-critical circumstances in patients with less severe disease or on a chronic basis. Clinical justification needs to be strong and explicit if one were to appeal insurer denials in this instance.

Other diagnoses

Few of the insurers would allow routine coverage for the remaining diagnoses, but some do. Even within Medicare, a program that generally succeeds in achieving national uniformity in policies, there is variation in coverage of specific diagnoses.⁴ The situation is similar among private insurers. There is lack of uniformity in coverage for multifocal motor neuropathy, neuropathy of paraproteinemia, myositis, postpolio syndrome, or Lambert-Eaton myasthenic syndrome. Diagnosis of these disorders is less straightforward, and they challenge both the neurologists and the payers. Some of them do not carry a specific ICD-9-CM code. This leads to difficulties with mechanistic claims processing.

Payers may not be aware of the nuances between dermatomyositis and inclusion body myositis. Payers may use ambiguous terms such as “myalgia” or “hereditary and idiopathic peripheral neuropathy” as indications for coverage. Both of these terms are either inexact diagnoses or diagnoses without clear indication or evidence for payment, yet they are currently being covered because the terms and codes have been entered into payers’ automated claims processing systems and

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therefore they are not stopped for review. Thus, payers could be diverting available funds to pay for unwarranted clinical situations.

Framework for appeals and review requests

Payers process a very large volume, range, and complexity of claims from all medical specialties. The onus is heavier on the providers than the payers to demonstrate that there are times when their patients' need falls outside of what is considered to be routine evaluation or treatment.

The potential for misunderstanding is high even at a medical review level, which occurs well past the automated claims processing stage. Generic advice, geared for any appeal, would also apply to this specific IVIg CPG:

- Ongoing and concurrent documentation of patient's status is vital. This will help with avoiding payer denials and with an appeal for "individual consideration." Careful payer staff reviewers read physician notes, nursing notes, and ancillary staff comments.
- Atypical clinical presentation, failure of other treatments, instability or rapidity of progression and support from published literature, even if not entirely evidence based, may aid in obtaining an affirmative coverage decision from a payer.
- Both providers and payers would find it helpful to remember that guidelines and policies focus on the needs of the average patient, circumstances, or setting. The unit of intervention in practice, however, is an individual patient, often with comorbidities, who could require customized care when the average intervention starts to fail.⁷⁻⁹
- A level-headed discussion with payers is worthwhile. Ambiguities in diagnostic criteria or terminology require dialogue, explanation, and clarification. Even with such careful preparation, coverage of individual cases is neither certain nor precedent-setting for subsequent appeals.

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DISCLOSURES

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