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Peg Skelly

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Billing for Off-label Drugs

by Peg Skelly

Q: *What are the basic steps for billing for a drug when it is not indicated for the disease?*

A: The steps will vary based on the patient's insurance, medical information supporting the use, state or federal off-label legislation, or local medical policy. Private insurers and Medicare have different claims submission and appeal requirements; however, the process is similar.

First, obtain up-to-date drug information for the off-label use. You want to know if the use (i.e., ICD-9-CM diagnosis code) is compendia indicated or undergoing compendia panel review, as well as the extent and type of supportive medical literature.

Next, contact the manufacturer to ensure you have the most current information available, especially when appealing. Check for updates when filing claims and again before filing an appeal. Ask the manufacturer for reimbursement and patient assistance information. Most manufacturers keep track of coverage policies for their products and may offer patient assistance if claims are denied.

Q: *What should I know about off-label legislation?*

A: Billing for off-label use should include an understanding of the applicable state or federal legislation and local medical policy. Effective January 1994, Medicare program contractors are subject to federal legislation for coverage determinations of unlabeled uses of FDA-approved drugs, including chemotherapy agents and drugs used to treat toxicities or side effects of the treatment.

Currently, thirty-five states have legislation prohibiting insurance companies and health maintenance organizations that provide coverage for prescription drugs from excluding coverage for off-label use of cancer drugs. In most states, off-label use recognized by compendia or peer-reviewed medical literature is covered. Even if state legislation does not apply to the off-label use, or if the plan is self-funded, the same information (i.e., compendia, medical literature) is considered by insurance companies in off-label coverage decision-making. Information on state off-label legislation is available through ACCC.

Q: *Are there specific steps to take when billing private insurers vs. Medicare?*

A: Prior to claims filing, call the insurer to verify coverage, or send a predetermination of coverage request. Provide a treatment plan along with product information and supporting medical literature. Be sure to closely monitor the insurer when coverage is unknown at the time of filing. If the claim is denied, call the insurer to confirm the reason for the denial. Oftentimes denials can be reversed on telephone review. For medical necessity denials, always confirm information requirements and the time frame for decision-making before filing an appeal.

Under Medicare, the patient is not liable for payment for services that are determined unreasonable or unnecessary where the patient could not have reasonably known that the services were not covered. In instances where coverage cannot be confirmed before treatment, consider a Waiver of Liability. By informing the patient in advance of treatment of the non-coverage potential, you are entitled to bill the patient for denied charges.

Q: *How does local medical policy affect coverage of off-label drugs?*

A: Medicare contractors develop and publish local medical policies (LMP) for specific drugs. When an off-label use claim is received outside of that contractor's LMP, the claim is denied and needs to go through the appeal process. When submitting claims for multiple patients, send a letter requesting policy for the off-label use to the contractor's medical director. Include drug information (package insert, compendia information, and medical literature) and send copies to the Carrier Advisory Committee (CAC) member for oncology and your state oncology society.

Q: *How do I appeal a denial of coverage?*

A: Keep track of time limits for filing appeals. Insurance plans vary, but Medicare appeals must be filed within six months of the processing date on the Explanation of Benefits (EOB) or Remittance Advice (RA). Although telephone reviews can resolve some denials, medical necessity denials must be appealed in writing. Prepare a letter of medical necessity and include supporting documentation (copies of RA, signed waiver, and product information). Key items to include are the patient's medical history and the rationale for the drug.

Peg Skelly is vice president of consulting services with Comprehensive Reimbursement Consultants in Minneapolis, Minn.