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Compliance considerations for manufacturer prior authorization programs

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Patient access to many therapies is constrained by limitations on coverage imposed by third-party payers. Prior to receiving an expensive therapy, to achieve certainty as to coverage, a patient may choose, or be compelled, as a condition of coverage, to seek prior authorization from their payer. This process can be complicated, and patients and providers may be ill-equipped or disinclined to navigate it. Consequently, many device and pharmaceutical companies run prior authorization support programs designed to help navigate the prior authorization process. In connection with these programs, manufacturers seek patient and provider permission and cooperation to advocate on behalf of patients for coverage from payers.

Before coverage parameters are well established by a payer (e.g., through a coverage policy or practice), manufacturer involvement facilitates the provision of healthcare economic information to the payer about the product and serves as a mechanism to allow the manufacturer to advocate for favorable coverage in the particular and more generally. Once coverage is well established, these programs seek to remove barriers to access by employing knowledge about payer approaches to coverage and resources to navigate payer processes. In short, these manufacturer-sponsored prior authorization programs allow manufacturers to use their resources and expertise to advocate for competitive, consistent, and timely coverage of their products and are particularly important in establishing and maintaining access to broad coverage for innovative, expensive therapies with restrictive coverage policies.

Manufactures have an evident, legitimate self-interest in running prior authorization support programs. They are motivated by a proper purpose: to establish and assure continuing and competitive third-party payer coverage for their products. Indeed, Section 502(a) of the Federal Food, Drug, and Cosmetic Act[1] recognizes a manufacturer's role in providing to payers truthful and accurate healthcare economic information about their drugs to make coverage and reimbursement decisions, which the United States Food and Drug Administration also expands to devices.[2] Without competitive and predictable coverage, initial adoption by providers may be dissuaded. Providers may shy away from recommending products with unpredictable coverage, as well as from products with place-of-service restrictions or reimbursement rates that make them less attractive to use than existing therapies. Thus, manufacturers have a strong interest in being involved in establishing coverage and its parameters, and prior authorization programs give them an avenue to do so.

Manufacturers' interests in facilitating prior authorization may continue even after predictable coverage is achieved. The burden of seeking prior authorization may interfere with patient access to the product. This particularly is the case for products that require a great deal of effort in order to obtain prior authorization. For

some products, with some payers, it is not uncommon for the process to routinely involve not only seeking prior authorization, but also appealing a negative decision through the payer's appeals process. Providers and patients are unlikely to have the resources, expertise, or incentives to pursue these burdensome processes.