
Auditor's Summary

Study of Proposed Mandatory Health Insurance Coverage Regarding Step Therapy Requirements for Stage 2 Through Stage 5 Cancer

Report No. 25-02



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WE WERE REQUESTED BY THE LEGISLATURE through House Concurrent Resolution No. 225 (Reg. Session 2024) to assess the social and financial effects of prohibiting insurers from requiring an insured diagnosed with stage 2 through stage 5 cancer to undergo step therapy prior to covering the drugs prescribed by the insured's health care provider, as proposed in Senate Bill No. 2316 (Reg. Session 2024) (SB 2316).

SB 2316 defines step therapy as “a protocol that requires an insured to use a prescription drug or sequence of prescription drugs, other than the drug that the insured's health care provider recommends for the insured's treatment, before the insurer provides coverage for the recommended prescription drug.” The bill will require insurers to provide coverage for drugs prescribed by the insured's health care provider that are: (1) investigational new drugs; or (2) FDA-approved drugs whose use is consistent with best practices for the treatment of that stage of cancer and is on the insurer's prescription drug formulary. Investigational new drugs are new drugs or

biological drugs that are not yet FDA-approved. Investigational new drugs are available through clinical trials and, with the drug manufacturer's approval, can be obtained through the manufacturer's expanded access programs.

We, however, did not assess the impacts of the proposed mandate relating to coverage of investigational drugs. Based on our research about investigational drugs and information from insurers that we surveyed, we were unable to reasonably estimate the likelihood that an insured diagnosed with stage 2 to stage 5 cancer can access an investigational drug and, if the insured does receive an investigational drug, the cost of that drug to the insured. Without that information, neither we nor the insurers could meaningfully assess the social or financial impacts of mandating coverage of investigational drugs for insureds diagnosed with stage 2 to stage 5 cancer.

What we found

Five insurers responded to our survey about the proposed mandate. Four of those insurers represented that they do not use step therapy protocols in covering prescription drug treatment for cancer. Those insurers provide health insurance coverage for about 80 percent of Hawai'i's residents. The fifth insurer stated that its network of providers applies appropriate guidelines developed by the American Society of Clinical Oncology and National Comprehensive Cancer Network that use sequential and escalating medication recommendations, which are, "in a form, step therapy." However, that insurer said that those guidelines are "very, very infrequently enforced" when a provider does not follow the therapeutic recommendations and cited two instances of such denials annually from 2021 through 2023.

With respect to the insurers that do not use step therapy protocols in covering drugs for insureds diagnosed with stage 2 to stage 5 cancer, we do not expect *any* material change to their current operations; we do not expect *any* material social or financial impacts to the insurers or their insureds. For those insurers, SB 2316 will serve to mandate the status quo.

The only insurer that currently uses step therapy protocols for treatment of cancer did not foresee any social impacts associated with the mandate in SB 2316. Similarly, that insurer did not believe that SB 2316 will result in any financial impacts.

Based on those responses to our survey, we conclude that there are no material social or financial impacts that will result from the health insurance mandate proposed in SB 2316.