

Health Plan Best Practice	Contextual Considerations
<p>1. Create coverage policies for targeted therapies after careful review of published scientific literature, practice guidelines, emerging evidence, and consultation with clinical experts and patient groups.</p>	<ul style="list-style-type: none"> • Limitations in clinical evidence include the lack of data from RCTs and follow-up time • May need to consider basket trials • Continued FDA approval may be contingent upon confirmatory trial(s) • Clinical experts may include local oncologists, large cancer treatment centers, and manufacturers • Use the clinicaltrials.gov database to stay up to date • Time to assemble and synthesize information can be considerable <p>Cautions Against</p> <ul style="list-style-type: none"> • Limiting coverage criteria to FDA-approved indications only <ul style="list-style-type: none"> • If the FDA label is used to guide coverage, engaging clinical experts and patient representatives becomes more valuable • Limiting coverage based on inclusion in practice guidelines/position statements <ul style="list-style-type: none"> • Data are published continuously and guidelines may not reflect current clinical practice standards
<p>2. Visual dashboards support drug value assessments of targeted therapies in oncology.</p>	<ul style="list-style-type: none"> • Evidence limitations due to under-representation of minority populations in clinical trials • Seek input on benefits/harms due to biological, cultural, or social reasons • Ensure coverage criteria have not gone beyond reasonable use of clinical trial inclusion/exclusion criteria
<p>3. Provider qualifications and site-of-care restrictions are appropriate in coverage criteria for ADCs to ensure patient safety.</p>	<ul style="list-style-type: none"> • Accurate diagnosis and use of ADCs require specialist training • Potential for serious side effects of therapy • Dosing, monitoring for side effects, and overall care coordination require specialist training • Site-of-care policies can be used to support safety and manage the costs of intravenous drugs
<p>4. Proactively provide coverage for and guidance on pre- and supportive medications for ADCs to prevent toxicity and adverse reactions.</p> <p>5. Proactively build decision support tools on ADC dose reductions to quickly addressing toxicity or adverse reactions.</p>	<ul style="list-style-type: none"> • Managing toxicities of ADCs are essential to their successful use • Unmanaged adverse effects may lead to treatment discontinuation • Ophthalmology-related care may be needed under the medical benefit if vision coverage is not available • Review UM on supportive medications (e.g., eye drops) and remove coverage barriers (e.g., quantity limits)
<p>6. Use multidisciplinary collaboratives or disease-specific working groups to better manage the growing complexity of cancer care.</p>	<ul style="list-style-type: none"> • Multidisciplinary teams can meet regularly to review clinical trial information • Teams can monitor trends, inform P&T, and support treatment pathways, including treatment sequencing • Teams can support understanding evolving clinical evidence more quickly and facilitate timely formulary/pathway updates
<p>7. Make clinical criteria and coverage policies for ADCs readily available to patients and providers on the payer website and provide rationale and references.</p>	<ul style="list-style-type: none"> • Clinicians and patients should be able to easily find criteria and supporting clinical rationale • Coverage policies are treated by some payers as competitive assets and held in confidence; while other payers post their coverage policies publicly • Greater transparency demonstrates a commitment to the appropriate application of clinical evidence to insurance coverage policies
<p>8. Use major compendia, clinical efficacy, side effects, and cost to build preferred pathways and treatment sequencing.</p>	<ul style="list-style-type: none"> • Maximize patient survival, minimize toxicity, and manage the total cost of care • NCCN treatment guidelines do not address the optimal sequencing • Increasingly complex with new agents and ongoing evidence gaps • Integrate treatment pathways into the EHR system to better support prescribing decisions
<p>9. Pharmacists and EHR case management modules support ADC-related care coordination and can help address social determinants of health.</p>	<ul style="list-style-type: none"> • EHR modules can increase administrative efficiency, coordinated care, and track patient outcomes over time • Pharmacists can recommend prophylactic medications to mitigate toxicity and follow-up with patients after infusions
<p>10. Patient education on adverse effects and supportive medications is an essential element of high-quality cancer care.</p>	<ul style="list-style-type: none"> • Patients need access to high-quality information, including cost and toxicities • Effective education requires an element of anticipation and preparation that can be easily missed if it is not incorporated into clinical workflows
<p>11. Optimal patient selection strategies require consideration of intratumor heterogeneity of target antigen expression and changes in expression with treatment and disease progression.</p>	<ul style="list-style-type: none"> • Patient selection based on tissue expression of target antigen • ADCs have also shown clinical activity in patients with low levels of target antigen expression
<p>12. Develop coverage policies that create a broader package of benefits so that patients who face financial or logistical hurdles can have equal access to specialized cancer care.</p>	<ul style="list-style-type: none"> • All stakeholders have a responsibility to reduce health inequities • Individuals at a higher risk of not receiving adequate education about their condition, face a longer time between diagnosis to initiation of any therapy, are often late to receive guidance regarding new treatment options, and may have trouble accessing highly specialized therapies • Expand telemedicine coverage and creating parity (e.g., out-of-pocket costs) between in-person and remote care • Recognize that, in addition to often steep out-of-pocket costs for cancer treatments, there are ancillary costs that can become barriers to care and exacerbate inequities.