

Gene Therapy Readiness Checklist

Key Payer considerations for proactively preparing and planning for the rising availability of Gene Therapy treatments



Benefit Assessment

- Does current therapy alignment match the plan's intent?
 - Medical vs. Pharmacy
- Is coverage duplicative?
 - Same therapies covered on both the medical and pharmacy benefit
 - Best suited for coverage under medical
- Are all currently FDA-approved gene therapies covered under the benefit?
 - If not, does that match the plan's intent for coverage?



Contract Assessment

- Request walkthrough with current vendor(s) to discuss contract details and reimbursement related to gene therapies
 - How are gene therapies being reimbursed?
 - Rates: by individual therapy or at the gene therapy class level?
 - How are ancillary/professional services reimbursed under the medical benefit: by service or global case rate?



Clinical Assessment

- Are prior authorizations in place for all covered therapies to confirm clinical appropriateness of use?
 - Do the criteria match the approved FDA label for use of any given therapy?
 - Off-label use should not have a pathway for approval
- Are prior authorizations in place for anticipated ancillary services associated with any given therapy?
 - Including but not limited to administration, adjunct procedures/medications, Inpatient or Outpatient services



Notification Process

- What is your preference for being notified regarding new gene therapy claimants?
 - Established utilization reviews vs. custom process
- If a custom process is desired, consider a starting point and ongoing cadence with your vendor(s)
 - PA approval, with a look back of every X days



Management & Monitoring Assessment

- What happens to the member following medication administration?
 - Confirm if case management is a part of the ongoing care plan
 - What is the frequency and duration of interactions?
 - Is reporting available?
- Does your vendor have policies in place for outcomes monitoring and reporting, following therapy?



Affordability/Risk Assessment

- What is the likelihood your plan may experience gene therapy utilization?
- Have you evaluated the financial impact to your plan, as a result of gene therapy utilization?
- Keeping in mind your plan's budget and current contractual pricing terms, are you content with the risk vs affordability continuum should your plan experience gene therapy claim(s)?

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