

CATALYST IMPLEMENTATION BRIEF

Access considerations for innovative treatments

This brief offers a checklist of key steps that different stakeholders should consider to ensure patients have access to innovative treatments. These therapies present unique challenges for different stakeholders and require collaboration between these parties to ensure that patients receive the best treatment for their condition. For additional background on this issue, see our prior [Implementation Brief describing key terms](#) for contracting and payment innovation.

What's covered

Access considerations for:

- Developers
- Payers
- Patients
- Providers

DEVELOPERS

Define the health outcomes and economic value of the new therapy. This analysis should express value for both patients and payers, comparing the new therapy to the prior standard of care.

Conduct market research with payers, providers, and patient advocacy groups to estimate demand for the new therapy. Such research can also provide insight into potential barriers to patient access.

Assess how pricing strategy may impact patient adoption. Consider how to balance attaining reimbursement for the innovation that went into the new therapy with the needs for affordability and patient access.

- This strategy should also plan to account for variations in payer coverage, provider demand, and patient acceptance.

Assess existing procedure and revenue codes. Determine eligibility for a [New Technology Add-on Payment \(NTAP\)](#) and timeline for an application to submit to CMS.

Align manufacturing and distribution processes to support the predicted utilization of the therapy.

Identify specific considerations for Medicare and Medicaid patients to access the therapy, then establish government price reporting processes as needed.

Develop a provider strategy to facilitate patient access. This may include:

- Facilitating provider education about the new therapy and how it compares to the current standard of care;

- If the therapy requires specialized expertise (such as cell and gene therapies), identifying qualified providers and facilities.
- Establishing a third-party distribution strategy if needed.

Develop a payer strategy. This may include:

- Facilitating payer education about the new therapy;
- Developing contracts with payers, including traditional contracts or innovative contracts. See the [key terms brief](#) for examples; future briefs will address innovative contracting in more detail.

Consider establishing patient support programs to facilitate treatment navigation as well as access for patients who are uninsured or under-insured.

If required, establish long-term follow-up studies. Collaborate with payers and providers to determine generally acceptable outcomes measures and track the therapy's effectiveness over time.

PAYERS

Implement a process for gathering information about new treatments, guidelines, and other clinical developments.

Assess a new therapy's clinical performance using clinical trial results and materials from the regulatory approval process. Developers may have information packages to support this review.

Identify the number of plan beneficiaries that may be eligible for the new therapy.

Predict potential provider demand and patient adoption of the new therapy to identify its actuarial impact or risk.

- See the [NEWDIGS FoCUS Individual Indication Pipeline Analysis Model](#) for resources that may assist in this assessment if the new therapy is a cell or gene therapy.

Define coverage policies and processes for the new therapy.

Assess financial risks and consider potential contracting strategies.

- Develop a multi-year view of treatment costs using different scenarios. Consider the impact of the treatment on the total cost of care at various price points.

Identify contracting strategies.

- For a traditional contract, consider rebate levels for medical coverage or formulary status.
- For a non-traditional contract, developers may offer a contract template for payers to consider. The [Value Based Contract Impact Assessment Model](#) may be a helpful resource in considering contract terms.

Ensure providers that are qualified to administer the new therapy are part of the plan network.

- Consider barriers to patients from plan design and, if needed, identify strategies to facilitate patient access.
- For example, if access to qualified providers is limited in a particular region, patients may face out-of-network charges to receive the therapy.

If outcomes tracking is required, identify data sources, processes, and resources needed.

Consider additional resources and/or third-party vendors to support any of these activities.

- Vendors may assist with care management, provider contracting, establishing financial strategies, collecting patient outcomes, and other aspects of delivering a new therapy to patients or meeting developer contract elements.

Self-insured employers should consider coordinating all of these steps with their broker or insurance carrier.

PATIENTS

Patients, in conjunction with their providers, should consider the following steps:

Identify unmet needs and consider the value of a new treatment compared to your current standard of care.

- Consider the new treatment's efficacy, safety, and cost. Providers and patient advocacy groups may be helpful resources in conducting this assessment.

Coordinate with your provider regarding treatment eligibility and your provider's capacity to administer the treatment.

- Work with your provider to ensure treatment eligibility requirements are met, such as specific test results or documentation.
- If your provider is unable to administer the treatment, a referral to another provider may be needed.

Coordinate with your payer regarding coverage eligibility, reimbursement, and cost-sharing for the treatment.

- Your provider and payer will also need to coordinate on these factors.

Identify your eligibility for patient support programs offered by the developer or payer, if such programs are available.

- Consider the potential out-of-pocket costs that you may face in paying for treatment.

Identify the potential impacts of travel, missed work, and missed income to receive the treatment. These impacts may also apply to other family members.

- Some employers and states offer paid family medical leave programs that can help income earners who must take time off work to receive treatment or to support a child or spouse receiving treatment.

Review the treatment journey with your provider to understand treatment expectations, including likely outcomes and side effects.

- Talk with your employer regarding the timeline for any potential change in insurance offered by the company that could occur during your treatment journey to avoid challenges in continuing or completing the treatment.

Participate in outcomes tracking by attending follow-up medical appointments and responding to correspondence from provider and payer.

PROVIDERS

Stay up to date on information about new treatment options relevant to your patients.

- Follow research, regulatory updates, and guidelines for new treatments. Developers may have information packets to support this review. Identify new treatments' potential impacts on current practice and prepare for discussion with patients who may be eligible.
- Consider identifying patients who are eligible for the new therapy and offering education or consultations to help them consider their options.

Identify resources needed to support administration of the new therapy.

- If required, hire or train staff to administer the new therapy. This may include medical staff, administrative staff, and regulatory compliance staff.
- Consider participation as a Center of Excellence, if required.

- Pursue training and qualification, if required.
- Identify processes and resources to support outcomes tracking, if required.

Anticipate payers' prior authorization or medical necessity requirements. Work with patients and payers to meet those requirements.

Identify reimbursement processes, including procedures that may be specific to novel durable therapies.

- For example, in delivering cell and gene therapies, providers may need to establish liability for the cost of drugs that are ordered through buy-and-bill programs, but not administered.

IN CONCLUSION

Preparation is required to ensure smooth access for patients to innovative therapies to address their unmet treatment needs. This preparation in most cases starts well before a new therapy is approved with anticipation of requirements and challenges. With communication and careful preparation on the part of each stakeholder, many of these barriers to patient access can be anticipated and addressed.

REFERENCES

[Integrated stakeholder views and challenges | Center for Biomedical System Design](#)

[Precision Financing Solutions for Durable / Potentially Curative Therapies | Center for Biomedical System Design](#)

[Payer and Developer perspectives on alternative payment models](#)

ABOUT NEWDIGS AT TUFTS MEDICAL CENTER

NEW Drug Development ParadIGmS (NEWDIGS) is dedicated to improving health out-comes by accelerating appropriate and timely access for patients to biomedical products, in ways that work for all stakeholders. NEWDIGS designs, evaluates, and catalyzes the real-world implementation of system innovations that are too complex and cross-cutting to be addressed by a single organization or market sector. Its members include global leaders from patient advocacy, payer organizations, biopharmaceutical companies, regulatory agencies, clinical care, academic research, and investment firms. For more information, visit newdigs.tuftsmedicalcenter.org.