DIGITAL THERAPEUTICS ALLIANCE

MARCH 2024

DTx Integration & Workflow Report

PURPOSE

1. Outline the workflow to integrate digital therapeutic products into the standard practice of care in the U.S.
2. Identify gaps or pain points in the workflow.
3. Propose the next steps to address the pain points to optimize the experience for clinicians and patients.

www.dtxalliance.org

ABOUT DTA

Digital Therapeutics Alliance (DTA) is a trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on digital therapeutic thought leadership and education, DTA provides policymakers, payors, clinicians, and patients with the necessary tools to evaluate and utilize DTx products.

MISSION

Broaden the understanding, adoption, and integration of clinically-evaluated digital therapeutics for patients, clinicians, payors, and policymakers through education, advocacy, and cross-industry collaboration.

Executive Summary

Digital therapeutics (DTx) have the ability to fill gaps in care for people and their families across the world. As a new category of medicine, one of the first barriers is the challenge of integration into the traditional healthcare system so that patients can receive access in a way that is convenient and consistent for them. This effort takes significant collaboration amongst diverse stakeholders across the complex healthcare system in the United States.

These stakeholders include policymakers from governing bodies, clinician and provider systems, health plans, pharmacies, DTx product manufacturers, and patients. However, there are many healthcare partners working behind the scenes to make it all work including pricing compendias and EHR vendors.

Over the last 18 months, DTA has worked with these stakeholders in close partnership with NCPDP to address identified pain points in the workflows. A critical barrier identified is understanding the payment pathways as it impacts each stakeholder downstream. Through the generous support of the NCPDP Foundation, DTA was awarded a grant to research how DTx products would be reimbursed. The research is included in this report.

We are proud of the efforts of our member task groups and other engaged stakeholders as we present this third DTx Integration & Workflow Report. While there is more work to be done, there is considerable positive direction in achieving the goal to integrate digital therapeutic products into the standard practice of care.

We are proud to solve barriers to patient access and invite you to join us in our efforts.

Andy Molnar
Chief Executive Officer
Digital Therapeutics Alliance

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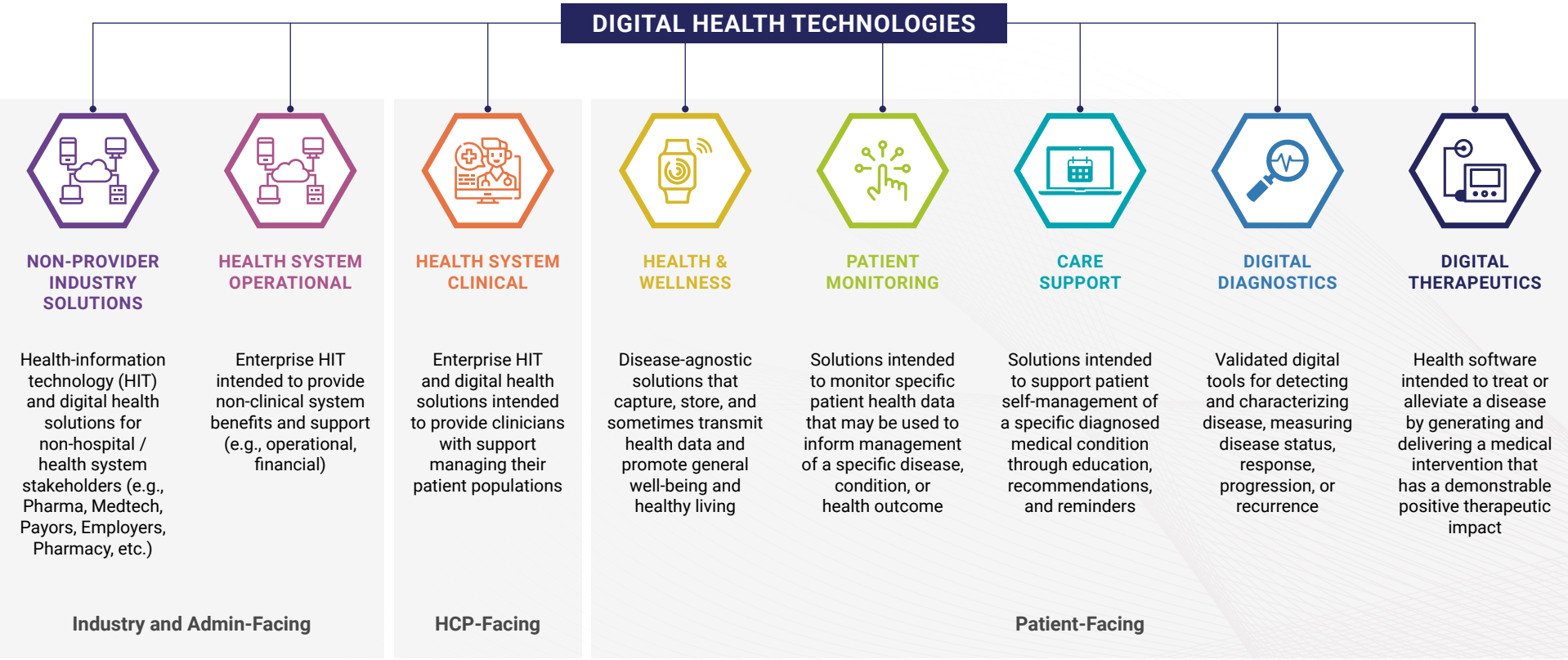
Understanding Digital Therapeutics

Digital Health Technologies Ecosystem

Digital health technologies include a wide variety of products ranging from IT to telehealth, tracking to diagnostics, wellness apps to digital therapeutics. Each has a role to play in supporting providers, payors, patients, and other healthcare stakeholders to achieve their goals. For the purpose of this report, we are focusing on digital therapeutics, referenced on the far right side of the diagram below.



About Digital Therapeutics

DTx products deliver to patients evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage, or prevent a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

According to ISO/TR 11147: Health Informatics - Personalized digital health - Digital therapeutics health software systems (2023), a digital therapeutic (DTx) is:

> Health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.

DTA's interpretation of the ISO definition is here: https://dtxalliance.org/wp-content/uploads/2023/06/DTA_FS_New-DTx-Definition.pdf.

Value in Patient Care

DTx products equip patients, clinicians, and payors with scalable, data-driven tools to address a wide range of diseases and disorders.

DTx products:

- Are accessible via smartphones, tablets, VR headsets, or other devices
- Deliver personalized medical interventions to patients in their preferred environments
- Are provided to patients through prescriptions or non-prescription authorization
- Provide secure, meaningful results and insights on patient goals, engagement, and outcomes
- Extend the reach of clinical care and improve health equity through standardizing therapy and enabling easier access

Within the digital therapeutics categories, there are prescription and non-prescription models.

Patients can access digital therapeutic products in a variety of ways depending on the condition addressed, the required interaction with a clinician, the risk involved in product use, and more. This is why there are prescription and non-prescription models. Regardless of the prescription or non-prescription route, products all have some sort of regulatory oversight and are evidence-based and clinically validated.

This report provides workflows for both prescription and non-prescription models for patients to access digital therapeutic products.

Approach to Discovery

In January 2023, DTA and NCPDP collaborated to host a workshop with 40 subject matter experts representing different perspectives of the flowcharts. During this two-day workshop, the SMEs reviewed, debated, and edited the flowchart previously created by DTA Advisor, DTA Task Group, and NCPDP Task Group contributors and developed a detailed narrative about the pain points, considerations for the pain points, and actionable next steps to resolve or mitigate the pain points. The collective group ended the workshop in alignment with the output of this report (see Closing Statement for references).

Since then, DTA Advisors, DTA Task Groups, NCPDP Task Groups have worked to address the identified pain points. A progress report was released in September of 2023 with the solutions addressed at that time. Additionally, NCPDP Foundation awarded DTA a grant to research and present how reimbursement pathways impact the work streams and identify where standardization already exists and opportunities for new standards.

There are important challenges for Digital Therapeutic product adoption including clear evaluation criteria and provider awareness and understanding of the products. Key assumptions for this report are listed below.

Key Assumptions	Notes
The product has appropriate clinical evidence.	» Sufficient clinical evidence varies depending on the condition, the population, regulation, and more » For support, reference DTA's Clinical Evidence Whitepaper
The product has been approved for your institution.	» Each institution has its own approval process » For support, reference DTA's DTx Value Assessment & Integration Guide
Clinicians are aware of DTx products and their place in care.	» There is a lack of awareness and understanding of DTx and its place in care for clinicians » A key initiative for DTA this year is clinician education

Findings: Pain Points, Considerations, and Next Steps

An overarching theme identified in the first iteration of the workflow pain points is that the reimbursement, or payment, pathway has significant influence on the workflows of the full ecosystem. It was critical that we uncover the challenges in the reimbursement and payment pathways in order to address the other pain points.

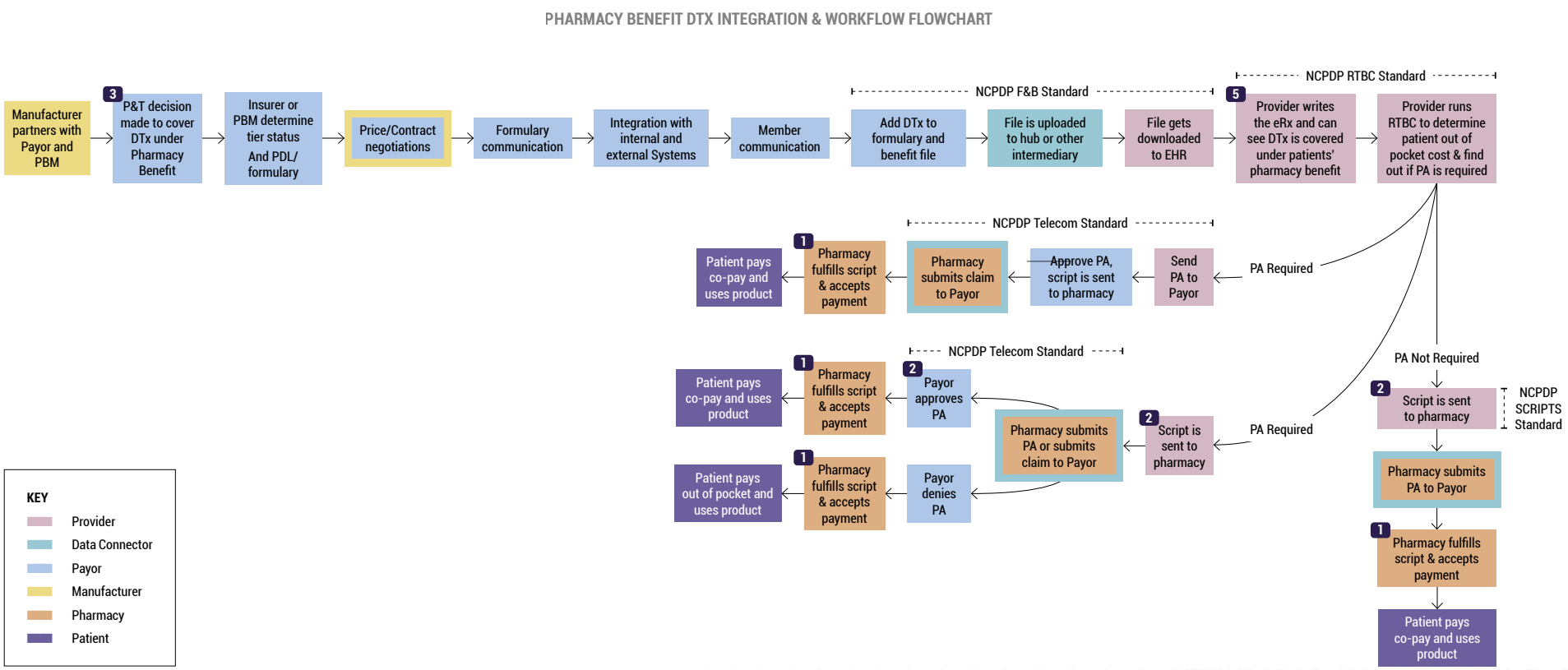
The approach was to first understand the reasoning behind a payor system assigning a product to a pharmacy benefit, medical benefit, or wellness category. We heard through our many interviews that this reasoning varies amongst payors and is subject to change. This table serves as a general guidance, not a rule.

Patient Access	Payor Category	Reasoning
Prescription	**Pharmacy Benefit**	» Most commonly used channel for other digital health products and point solution offerings » NDCs can be used as a method to get products included into existing adjudication systems » Product can follow similar pathway as drugs » Product is self administered » Product has a good partner for patient support with a dispensing pharmacy » May follow the FDA pathway » Are therapeutic products (as opposed to medical services or equipment) » Unique reimbursement codes which fit well with existing claims infrastructure » Standardized products (i.e., same product and same quality for each patient) with predictable and transparent list price and clear negotiated net price » Depends on payor line of business » Speed of insurance approvals is expedited relative to medical benefit » Included in all major drug compendia

Patient Access	Payor Category	Reasoning
Prescription	**Medical Benefit**	» Could or must be administered by the clinician » Product doesn't have patient support through a pharmacy » Product acts as more of a service » You have to reach out to the clinician and it costs more money » Product can be used only on proprietary hardware » There is a unique Durable Medical Equipment (DME) code with appropriate reimbursement » Depends on payor line of business
Non-Prescription	**Other/Wellness Benefit**	» Employer requests » Vendor relationship

Following this exercise, we detailed the workstreams of each of the categories.

Prescription Models



Pharmacy Benefit Map Detail

Drug Review and Assessment:

» Clinical Evaluation: The PBM's pharmacy and therapeutics (P&T) committee reviews the new drug's clinical data, efficacy, safety, and potential patient population

» Cost-Benefit Analysis: Evaluate the drug's cost-effectiveness and its potential impact on the PBM's overall drug spend

Formulary Placement Decision:

» Tier Assignment:

— Determine the tier at which the drug will be placed within the formulary. This influences patient copayments

— Prior Authorization: Decide if the drug will require prior authorization, which means prescribers must provide additional clinical information before it's covered

» Contract Negotiations:

— Price Negotiation: Negotiate pricing agreements with the pharmaceutical manufacturer to determine the cost of the drug for the PBM

— Terms and Conditions: Establish contract terms, including rebate agreements, distribution, and supply chain details.

Formulary Communication:

— Notify Clients and Members: Inform clients (health plans, employers, etc.) and plan members about the addition of the new drug to the formulary

— Pharmacy and Provider Outreach: Educate pharmacies and healthcare providers about the formulary change and any related processes

Integration with Systems:

» Update Formulary Data: Ensure that the drug information is accurately updated in the PBM's systems and accessible to healthcare providers and pharmacists

» Claims Processing: Modify claims processing systems to include the new drug and apply appropriate pricing and coverage rules

Member Communication:

» Member Outreach: Notify plan members about the addition, including any changes in copayments or coverage requirements

» Patient Education: Provide information to patients about the new drug, its benefits, and any necessary steps for access

Monitoring and Evaluation:

» Ongoing Assessment: Continuously monitor the drug's utilization, safety, and effectiveness.

» Adverse Event Reporting: Establish mechanisms for reporting and managing adverse events associated with the new drug

» Cost Control: Continually assess the drug's impact on the PBM's budget and adjust strategies if needed

Quality Assurance:

» Quality Metrics: Set quality measures and benchmarks to ensure the drug meets established clinical and cost-effectiveness standards

» Regular Audits: Conduct audits and reviews to ensure compliance with formulary and contractual agreements.

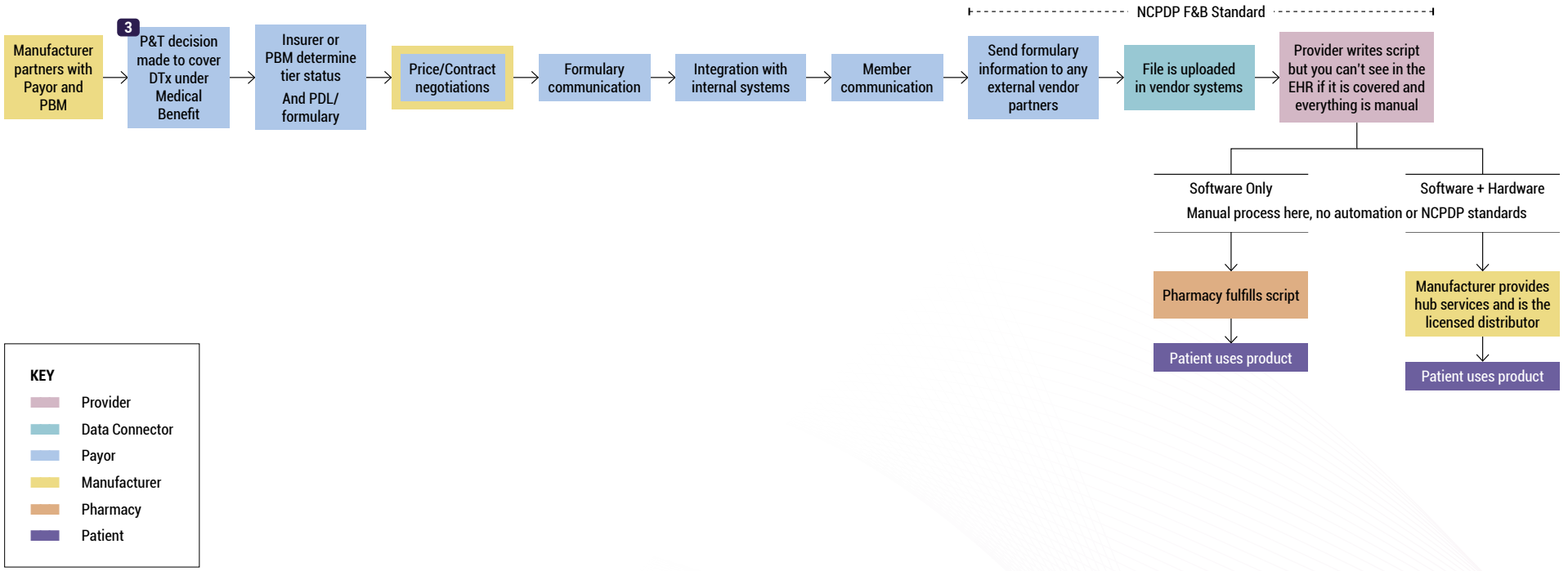
Feedback Loop:

» Stakeholder Input: Gather feedback from healthcare providers, pharmacists, and plan members to improve the process and address any concerns or issues

Review and Updates:

» Periodically review the drug's performance and consider adjustments to its placement, coverage criteria, or pricing

MEDICAL BENEFIT DTX INTEGRATION & WORKFLOW FLOWCHART



Medical Benefit Map Detail

Drug Review and Assessment:

» Clinical Evaluation: The medical plan's pharmacy and therapeutics (P&T) committee or clinical review board assesses the new drug's clinical data, efficacy, safety, and potential patient population

» Cost-Benefit Analysis: Evaluate the drug's cost-effectiveness and its potential impact on the medical plan's overall healthcare costs

Formulary Placement Decision:

» Tier Assignment: Determine the tier at which the drug will be placed within the formulary, influencing patient cost-sharing (eg, copayments or coinsurance)

» Coverage Criteria: Define any specific criteria, such as prior authorization or step therapy requirements, for the drug's use

Contract Negotiations:

» Negotiate with Manufacturers: Negotiate pricing agreements and rebate arrangements with the pharmaceutical manufacturer to determine the drug's cost to the medical plan

» Contract Terms: Establish contract terms, including distribution, supply chain logistics, and performance metrics

Formulary Communication:

» Plan Member Notification: Inform plan members about the addition of the new drug to the formulary, including any changes in out-of-pocket costs

» Provider Outreach: Educate healthcare providers about the formulary change and any new requirements for prescribing the drug

Integration with Systems:

» Update Formulary Data: Ensure that the new drug's information is accurately updated in the internal health plans systems

» Claims Processing: Modify claims processing systems to incorporate the new drug, its pricing, and coverage rules, including edits if applicable

Member Communication:

» Member Education: Provide information to plan members about the new drug, its therapeutic benefits, and the steps required to access it

» Out-of-Pocket Costs: Clearly communicate any changes in patient cost-sharing for the new drug

Monitoring and Evaluation:

» Ongoing Assessment: Continuously monitor the drug's utilization, clinical outcomes, and cost impact

» Adverse Event Reporting: Implement mechanisms for reporting and managing adverse events associated with the new drug

» Cost Management: Regularly evaluate the drug's effect on the medical plan's budget and consider adjustments if necessary

Quality Assurance:

» Quality Metrics: Define quality measures and benchmarks to ensure that the drug meets established clinical and cost-effectiveness standards

» Regular Audits: Conduct audits and reviews to ensure compliance with formulary and contractual agreements

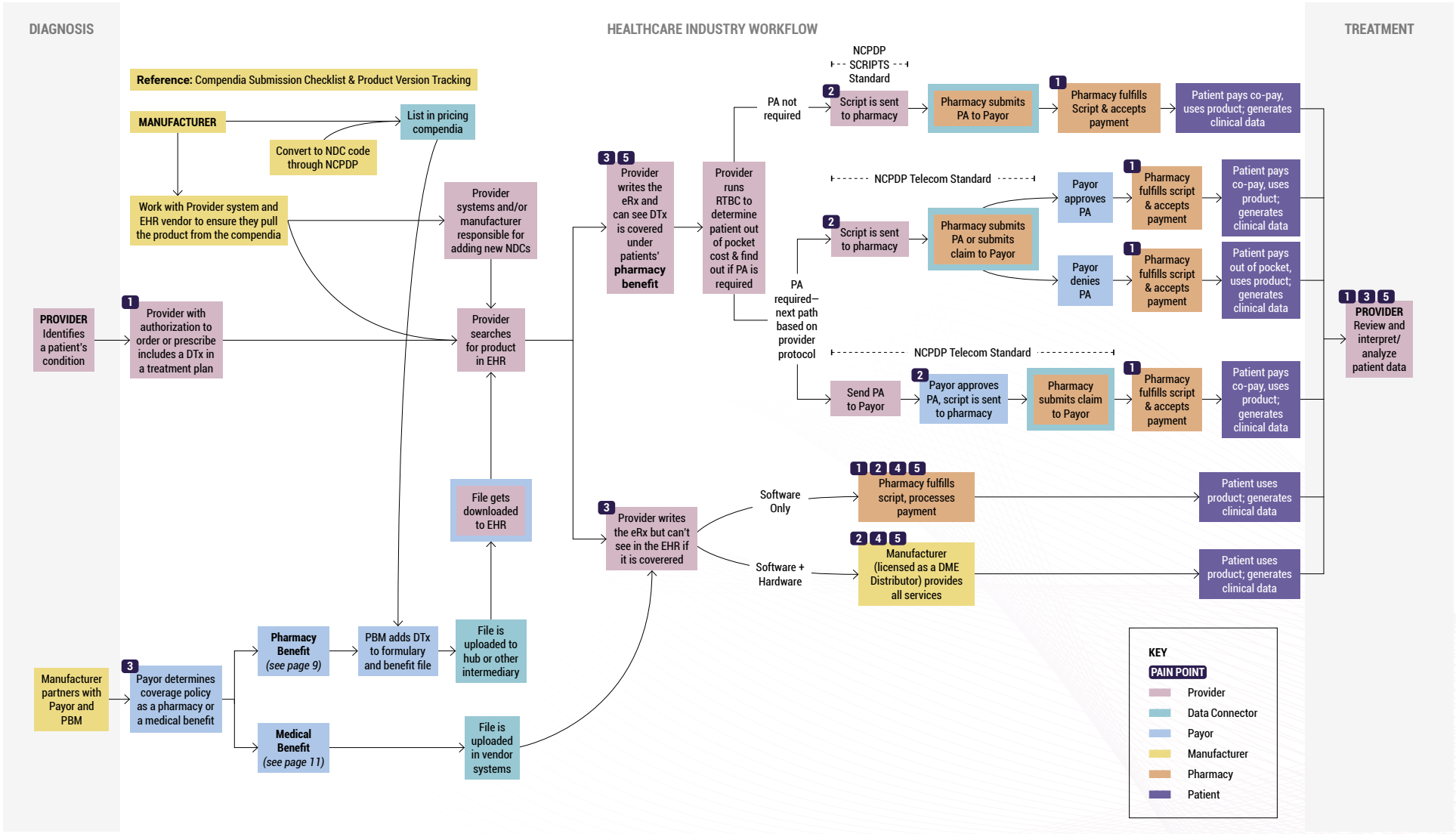
Feedback Loop:

» Stakeholder Input: Gather feedback from healthcare providers, pharmacists, and plan members to continuously improve the drug addition process and address concerns or issues

Review and Updates:

» Periodically review the drug's performance and consider adjustments to its formulary placement, coverage criteria, or pricing

2024 Prescription Workflow



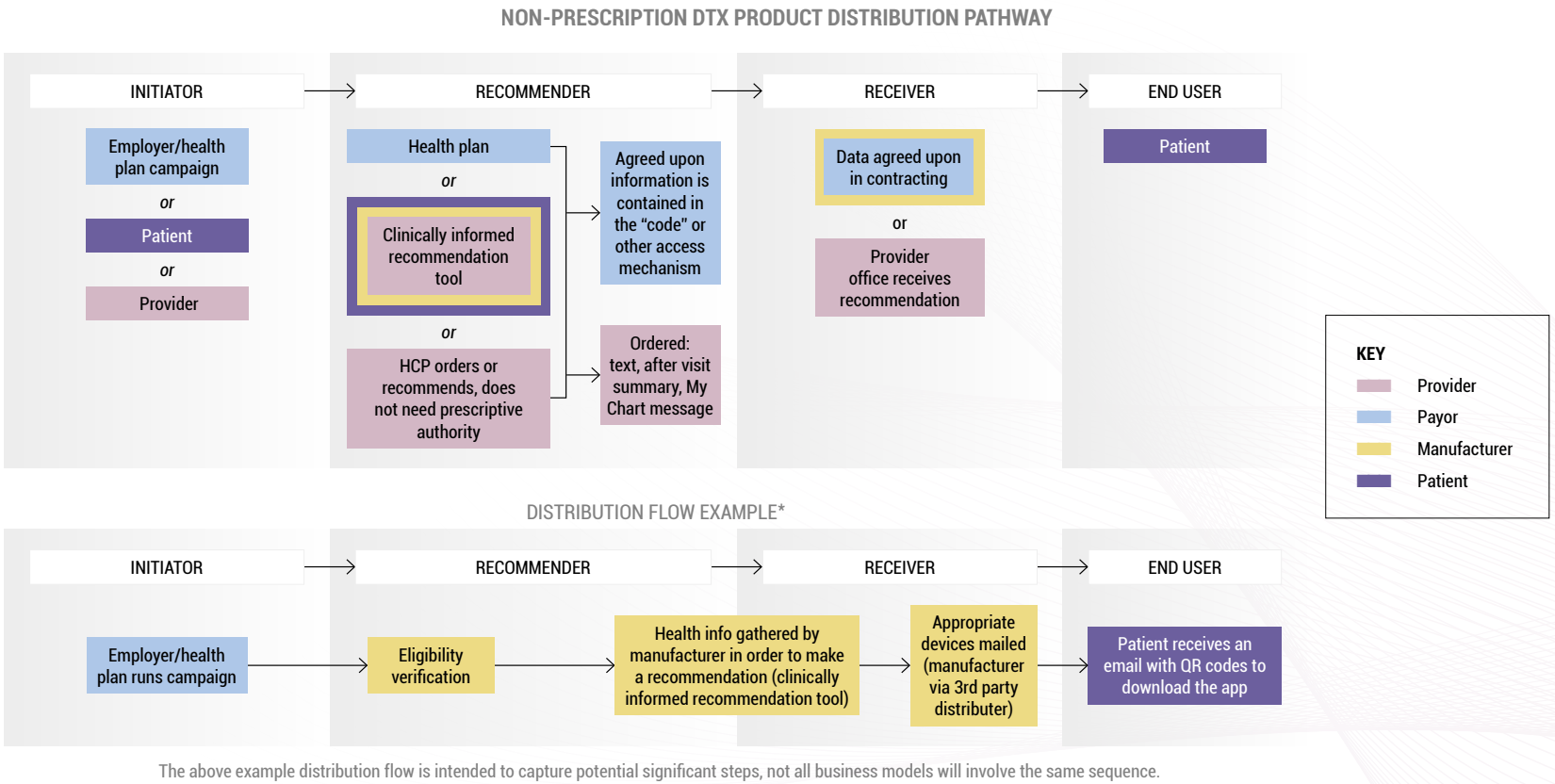
Prescription Pathway Pain Points

Pain Point	Considerations	Next Steps
1 The scope of professionals who are involved is not clearly defined	» What scope of professionals can order? This varies by state, varies by submission (label) to FDA » What scope of professionals can sign? » What scope of professionals can release/fulfill? » What is the place order and place of release/fulfillment? In the office in real time or with a pharmacist? Virtual? » What scope of professionals will monitor the treatment?	DTA Clinician Education Task Group to research
2 Distribution networks are not standardized	» Distribution depends on whether the product is software only or software + device » Distribution is not standardized—it can come from a non dispensing pharmacy, specialty pharmacy, from the manufacturer » Very few distributors are trained in DTx » Dispensing pharmacies need to be in insurance network » No standardized way to provide patients the product activation code	DTA Integration & Workflow Task Group researching

Pain Point	Considerations	Next Steps
3 Lack of and inconsistent coverage by Medicare, Medicaid, and commercial health plans	» Medicare does not cover software-only products » Nature of commercial health plans - employer based » PBMs need to list them on their formularies » Some plans may have the opportunity to tie DTx to wellness programs » Insufficient coding (HCPCS and CPT) » Value-based arrangements could influence adoption however would be unique to each institution	» DTA Policy Task Group to drive legislation for CMS to cover DTx products » DTA Policy & Commercial Task Groups to work with state Medicaid programs because of their flexibility outside of federal legislation » DTA Commercial Task Group to work with commercial health plans, PBMs, and Employers on evaluation frameworks, challenges, industry expectations, and plan designs » DTA Policy Task Group to work with CMS and AMA to develop new product and service codes » DTA Commercial Task Group to research VBC opportunities with health plans
4 Medical Benefit Pathway has no automation	» This is a pain point for specialty drugs, DME products, and other products and procedures that fall in this category » Lack of price transparency for patients » Manual and arduous process for all stakeholders	DTA to research this shared pain point in more detail
5 Outcomes (clinical) data feedback loop	DTx products generate vast amounts of data but there is no structured way for payors and providers to review the aggregated data in real time	DTA to research this pain point with health systems and data aggregators (vendors)

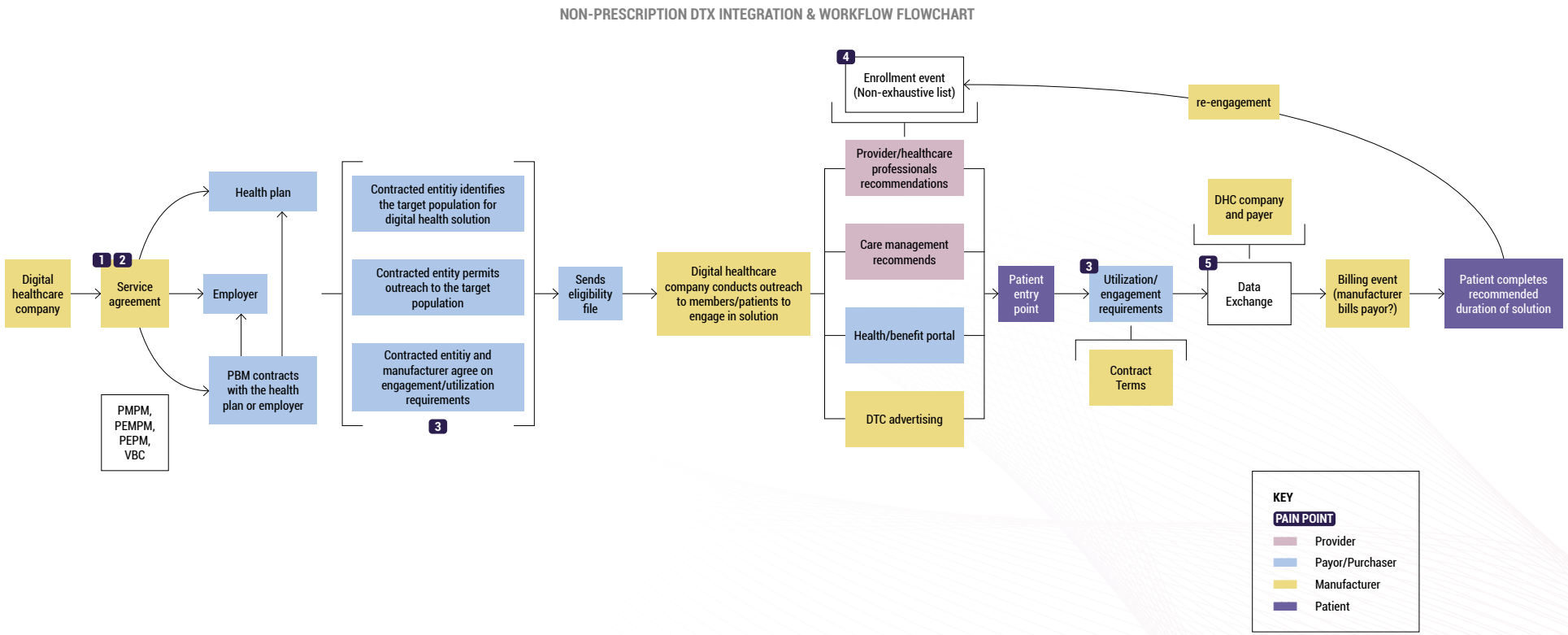
Non-Prescription Models

The distribution landscape for non-prescription DTx products is characterized by an increasingly accessible and consumer-centric approach. These products are often available through mobile applications, online platforms, or over-the-counter channels. The distribution of non-prescription DTx products involves a network of key stakeholders. Digital health companies are at the forefront and often enter into contracts with employers/benefits managers. Healthcare providers and professionals may also have a role, as they may recommend specific non-prescription DTx solutions for their patients. Patients themselves are key stakeholders, as their awareness, preferences, and feedback shape the demand and utilization of non-prescription DTx products. When thinking about the visual representation of distribution below, keep in mind that for each stage of the flow the actors involved may differ, or not apply in each situation.



The above example distribution flow is intended to capture potential significant steps, not all business models will involve the same sequence.

2024 Non-Prescription Workflow



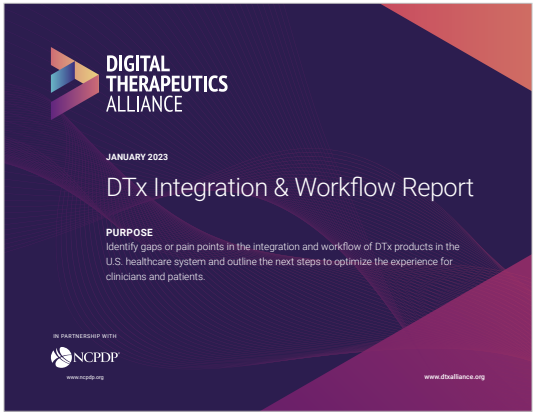
Non-Prescription Pathway Pain Points

Pain Point	Update	Next Steps
1 Manufacturers are not easily able to identify the key decision maker in payor organization.	In order to establish scope of work, clinicians of all types need to understand and trust the products they are working with. To meet this need, USP is conducting research and engaging stakeholders to address the gaps in standards intended to approve quality metrics with prescribed products. The outcomes of a recent DTx panel involving experts across industry, healthcare and academia are currently being published while ongoing research continues.	Link to provide commentary to published summary of DTx Panel at USP will be available to the public shortly.
2 Alignment on Contracting.	There are many parts to a service agreement (contract)—streamlining on data sharing, risk components, terms and conditions and rates/cost can delay execution.	» Illustrate contract timelines. » Create service agreement template(s) taking into consideration differences between public payor, commercial payor, regional payor.
3 Definition of engagement is inconsistent.	Aligning on key examples for patient/member engagement with DHC solution: what are standardized examples that can apply across companies and be aligned by payors?	Determine commonalities regarding patient engagement via manufacturer survey/interview.
4 Enrollment Event/Getting members on the DHC solution is inconsistent.	Alignment on population and agreement on joint promotion between (health plan/employer/manufacturer) can maximize uptake.	Outline a framework of strategies that may be effective in the distribution workflow.
5 Integration with other payor solutions.	Does the new data generated and captured by the DHC solution aid with payor needs—whether that information is integrated in care management, supplied to providers' EHR, etc. Can the DHC solution synergize with payors current efforts of care gap closure?	Define feedback loop in conjunction with prescription workflow group.

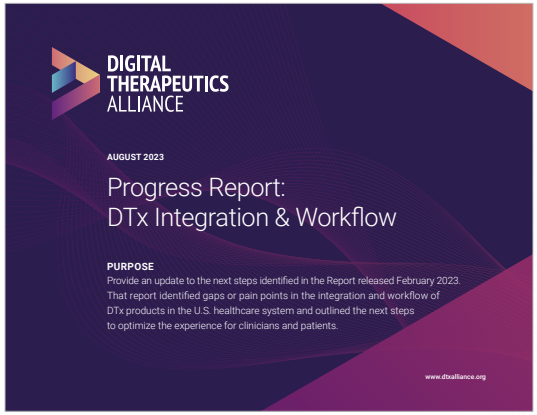
Closing Statement

In closing, DTA is proud of the work of it's members and the full healthcare system ecosystem to solve for pain points as the world innovates to make healthcare more accessible and of higher quality for patients and their families. We will continue to address the issues raised and any others that are found that prevent a positive experience for patients, payors, and providers.

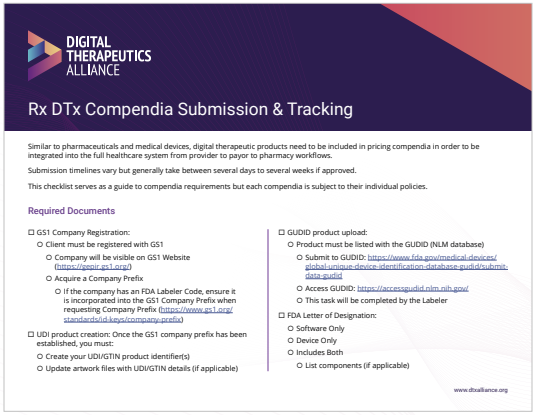
If you have questions around the presented workflows, please see the following references:



U.S. DTx Workflow & Integration Report (January 2023)



U.S. DTx Workflow & Integration Progress Report (August 2023)



Rx DTx Compendia Submission & Tracking (August 2023)

If you have additional questions or would like to learn more about the workflow and how to address the pain points, please contact us at info@dtxalliance.org.

Thank You

DTA Clinician Advisory Group

DTA Payor Advisory Board

DTA Patient Advisory Council

DTA Integration & Workflow Task Group

DTA Commercialization Task Group

NCPDP DTx Task Group

NCPDP Foundation

Point-of-Care-Partners

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