DIGITAL THERAPEUTICS ALLIANCE

SEPTEMBER 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 recommendations to optimize healthcare workflows and patient experiences.

www.dtxalliance.org

ABOUT DTA

Digital Therapeutics Alliance 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, the Digital Therapeutics Alliance 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 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 parties across the complex healthcare system in the United States.

These parties 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 two years, 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 they impact each stakeholder downstream. Through the generous support of the NCPDP Foundation, DTA was awarded a grant to research how DTx products would be reimbursed. Following the reimbursement workflows, we were able to finish the outline by addressing the distribution of the products into the hands of patients and their families.

We are proud of the efforts of our member task groups and other engaged stakeholders as we present this fourth and final DTx Integration & Workflow Report. While there are recommendations to improve the aspects of the healthcare system, we have been able to achieve our goal to outline how 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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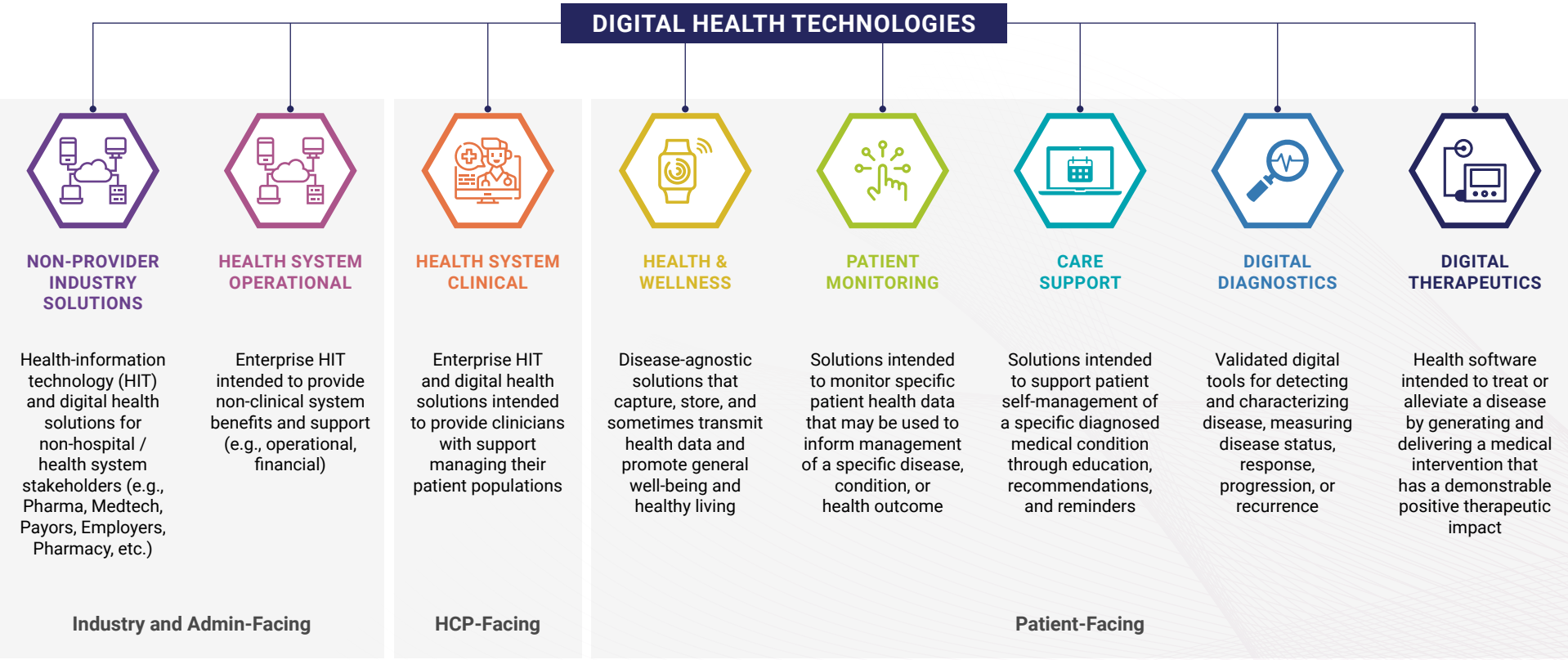
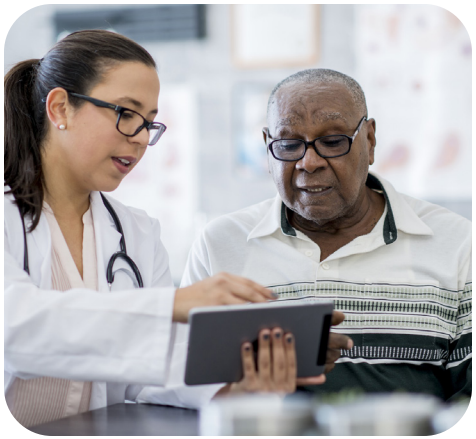
Understanding Digital Therapeutics

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

Digital therapeutic products (DTx) 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

DTx at a Glance

- Evidence-based and clinically validated by peer-reviewed clinical trials
- Use clinical endpoints to measure efficacy
- Make a medical claim to treat, manage, or prevent a disease or disorder
- Deliver an intervention directly to the patient *by software*

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 National Council for Prescription Drug Programs (NCPDP) collaborated to host a workshop with 40 subject matter experts representing different perspectives of healthcare stakeholders. During this two-day workshop, the SMEs reviewed, debated, and edited the workflows 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 first report that was released in February 2023.

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 and then in March 2024 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 DTx adoption including clear evaluation criteria and provider awareness and understanding of the products. Key assumptions for this report are listed here:

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

Payment Pathways as a Primary Driver of Workflow Differentiation

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—Product Characteristics	Reasoning—Health Plan Philosophy
Prescription	**Pharmacy Benefit**	» Drug-like codes can be used as a method to get products included into existing adjudication systems » 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) » Standardized products (i.e., same product and same quality for each patient) with predictable and transparent list price and clear negotiated net price » Included in all major drug compendia	» Depends on payor budget » Speed of insurance approvals is expedited relative to medical benefit

Patient Access	Payor Category	Reasoning—Product Characteristics	Reasoning—Health Plan Philosophy
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 » Product can be used only on proprietary hardware » There is a unique Durable Medical Equipment (DME) code with appropriate reimbursement	» Depends on payor budget
Non-Prescription	**Employer/ Wellness Benefit**	» Clinician prescription is not necessary » Business model makes the product more easily accessible » Provider as a distribution channel (optional)	» Employer requests » Vendor relationship

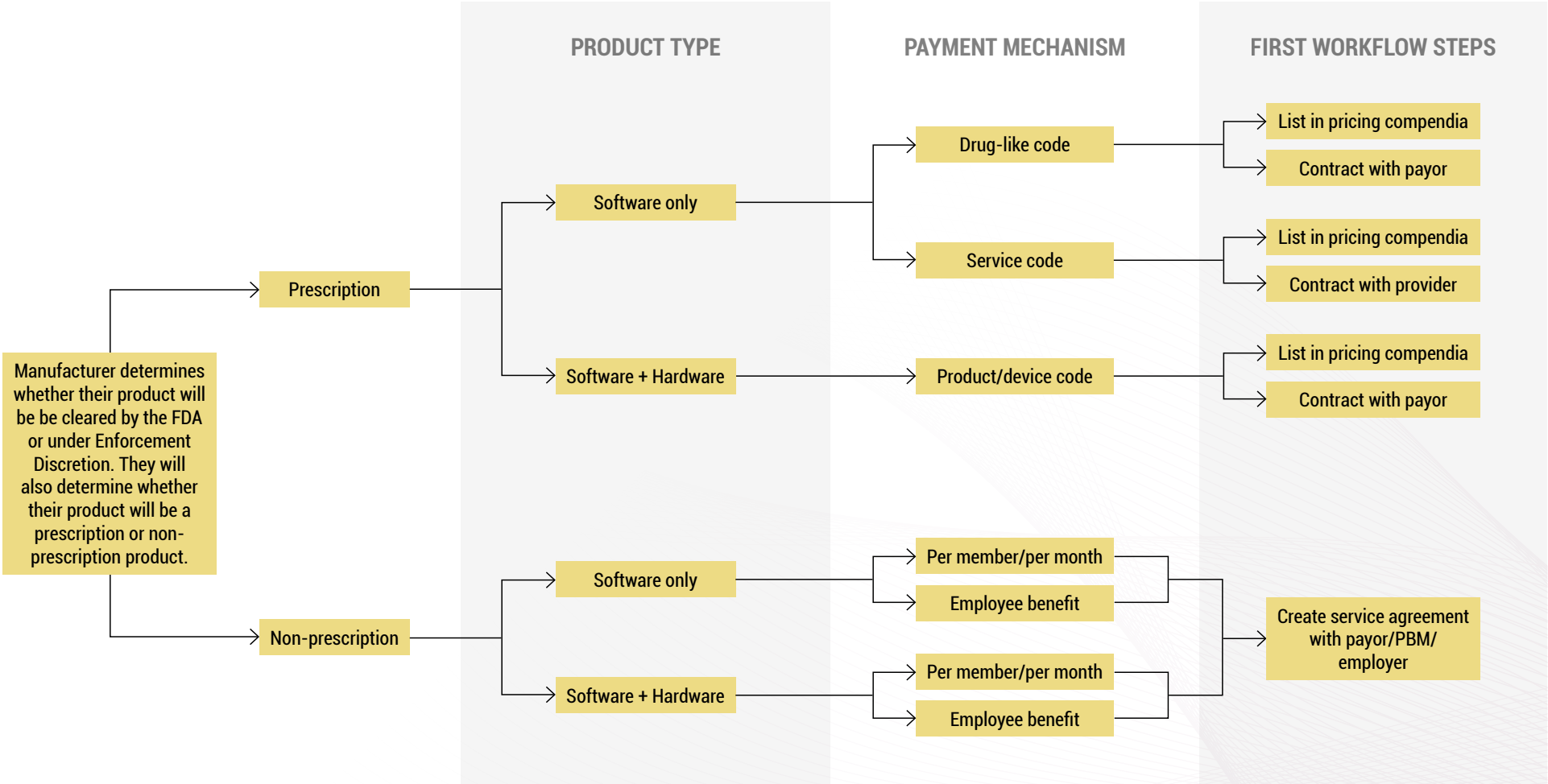
Findings: Setting the Stage

As DTx manufacturing companies develop their product there are some key considerations that they need to think through as it relates to integration and workflow. One consideration is appropriate FDA oversight. Generally, prescription products achieve a 510(k) FDA clearance while non-prescription products have lighter FDA oversight through Enforcement Discretion or, as we saw through the pandemic, Emergency Use Authorization. These two different pathways are critical to understand how they will ultimately reach patients because of the different stakeholders that are at play when a product is prescribed by an authorized provider and then they are offered by a health plan or employer benefits.

Both prescription and non-prescription products may come as software only or come with a hardware component. This also plays a role in the payment mechanism and workflow. To date, software only prescription products have been paid for using drug-like 11-digit codes (may be called NCPDP Product Identifier) or CPT codes. Prescription products with a hardware component have been paid for using a HCPCS code and use a durable medical equipment (DME) reimbursement mechanism. Non-prescription products also may be software only or software plus a hardware component. Traditionally these products are reimbursed or paid for by health plans or employer benefits.

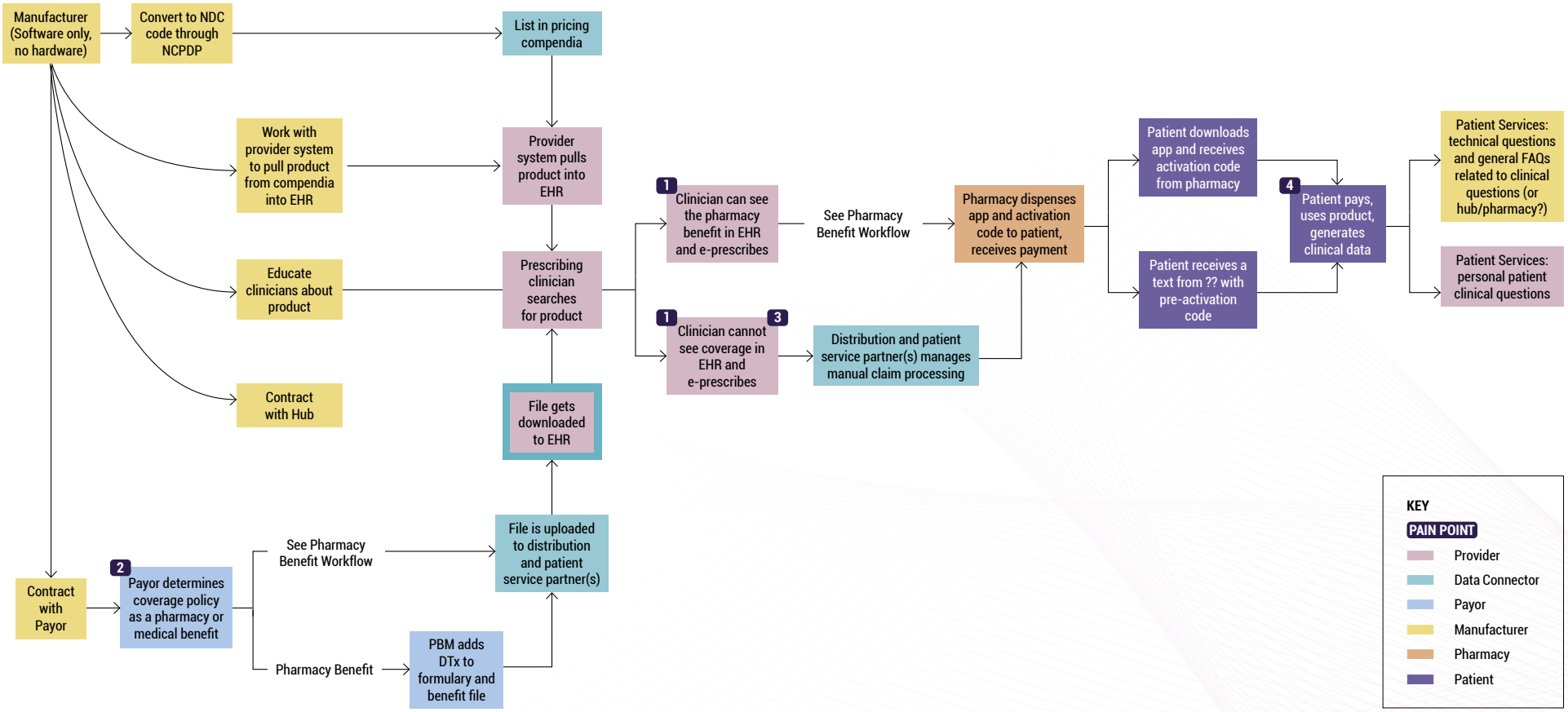
As this report continues, it will outline the workflows according to their payment pathways. Iit is very important to understand and plan for these differentiation as you look towards the upcoming workflow.

Workflows Are Impacted by Product Type and Payment Mechanism



Prescription Models—by Reimbursement Type

Drug-Like Code



Pharmacy and Medical Benefit Workflows are on pages 30–33.

Drug-Like Code Detail

For products that are software only and that are prescription in nature the manufacturer has to start by converting their GUDID and UDIs that are provided by the FDA into an 11-digit code that can be used by each stakeholder group through the workflow. This conversion goes through NCPDP. Use the DTA Compendia Submission Checklist on page 28 about how to prepare to submit to be listed in a pricing compendia so that a provider system may pull the listing into it's EHR.

Once the product is listed in the compendia, the manufacturer will work with the provider systems so that they will select their product as one to pull into their EHR for their clinicians. It is the responsibility of the manufacturer to provide education for individual clinicians about their product as well.

In this instance, since the prescribed product needs to be dispensed, the manufacturer needs to contract with distribution and patient service partners, that will serve as the prescription and payment processor and will dispense the activation code. This third party may also provide additional patient services.

The manufacturer also has to contract directly with the health plan to cover their products as a pharmacy or a medical benefit. Detailed outlines of the pharmacy and medical benefit workflows are on pages 30–33. For this section, we will skip the details.

First, we will consider the pathway if it is a pharmacy benefit. As a pharmacy benefit the PBM will add the digital therapeutic product to the formulary and benefit file. Once that has been completed the file has been uploaded to the distribution and patient service partners then that file gets downloaded to the EHR.

Since the product information has been pulled into the EHR and now the coverage information has been pulled into the EHR, the prescribing clinician can search for the product in their EHR as is their standard practice. In this pathway the product is covered as a pharmacy benefit so the clinician can usually see that the product is covered in their EHR and they e-prescribe the product.

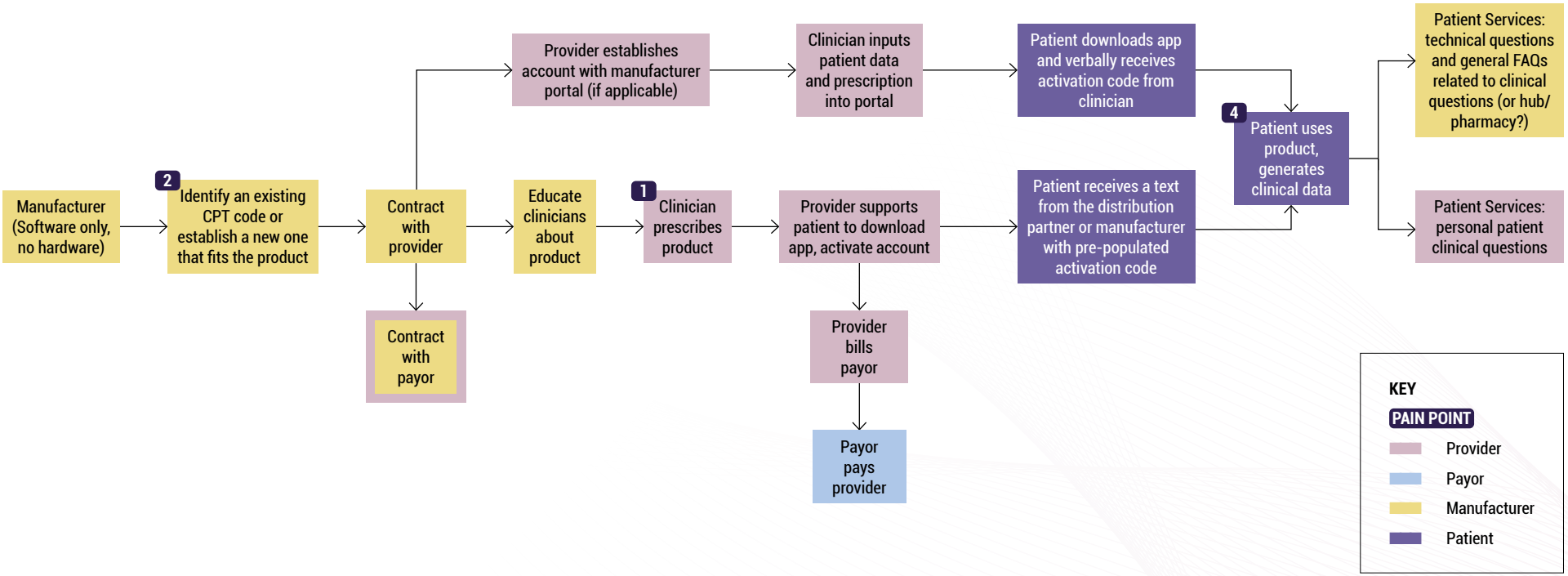
Next, we will consider the pathway if it is a medical benefit. If it's a medical benefit, the file is uploaded to the hub or other intermediary the same as a pharmacy benefit. Generally for medical benefits, the clinician cannot see the coverage in the EHR but they can still e-prescribe anyway. The distribution and patient service partners manages the manual claim processing that is needed to take place.

In either circumstance whether the product is covered as a pharmacy or a medical benefit , once the product has been prescribed, the distribution and patient service partners dispenses the DTx and activation code for the patient. They also receive payment in the form of a copay or deductible at that time. The patient downloads the app and enters the activation code They may also download the app through a link that could already have the activation code in it. This activation process varies by manufacturer.

Then the patient uses the DTx and generates clinical data. Patient services can be put into two categories:

- General questions are the responsibility of the product manufacturer
- Specific questions related to a patient's personal health are the responsibility of the prescribing clinician

Service Code



Service Code Detail

CPT codes are developed and licensed by the American Medical Association. If your product qualifies as a service by a provider that can be reimbursed using a CPT code this route for reimbursement may be an option for you and your products.

First the manufacturer develops a relationship and contracts with the provider. In some instances, a manufacturer may decide to become a licensed provider. They will identify an existing CPT code or work to establish a new code (this can take a considerable amount of time and expense). If we assume that there is an existing CPT code, you will develop a contract with the provider about the use and pricing of the product that fits within the CPT code price. The provider is responsible for a contract with the health plan to make sure that the health plan will reimburse them for the use of your product.

When the provider is ready to prescribe the DTx there are a couple of different pathways in the workflow that vary amongst manufacturers. The first path is through a portal. If your company has a portal the provider may log in, enter the patient information and prescribe the product to the patient. From there the patient would download the app and verbally receive an activation code from the provider at that time or receive a link to the app with pre-populated activation codes. If there is no portal the clinician could prescribe the product and would support the patient to download the app and activate the account. The patient could receive a text with pre-populated activation code. Once the patient receives or downloads the app with the activation code then the patient is ready to use the product and generate clinical data.

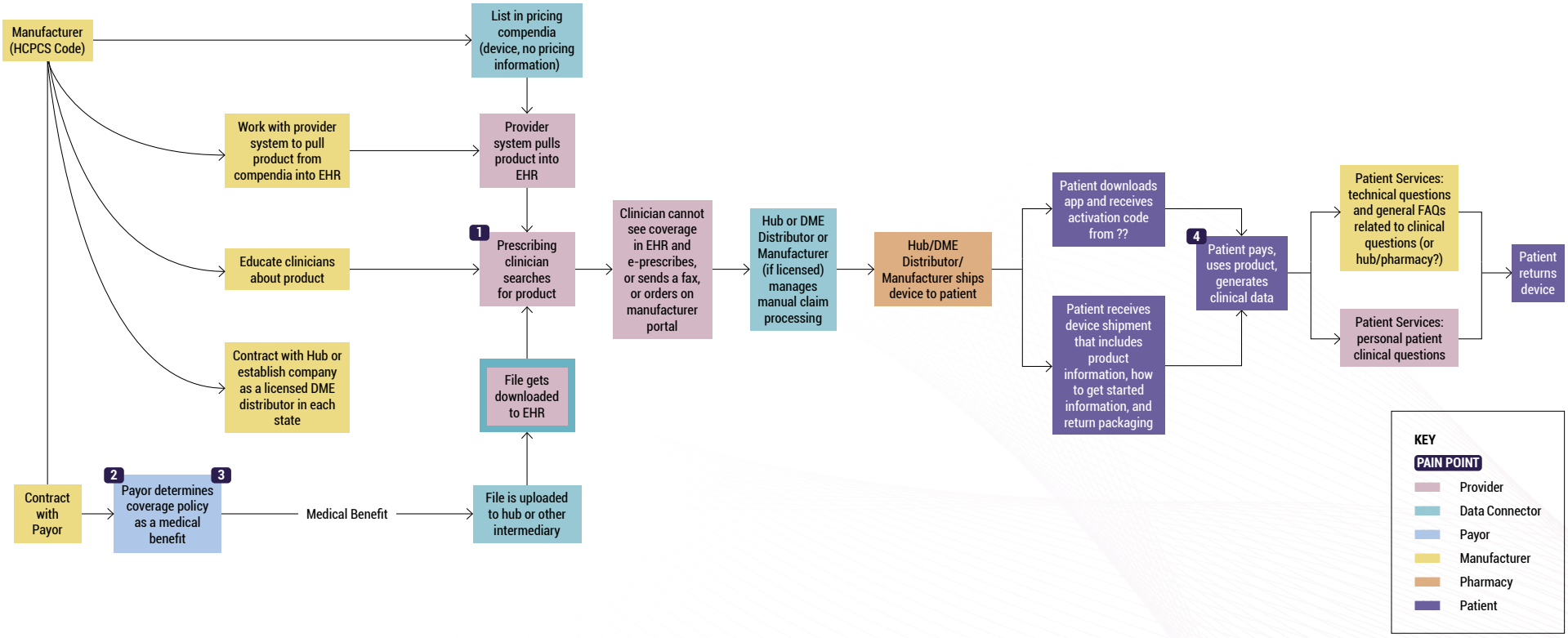
Then the patient uses the product and generates clinical data. Patient services can be put into two categories:

» General questions are the responsibility of the product manufacturer

» Specific questions related to a patient's personal health are the responsibility of the prescribing clinician

In terms of reimbursement, the provider will bill the health plan for the service/product and the health plan will pay the provider.

Product/Device



Product/Device Detail

Products that have a hardware component are often reimbursed as durable medical equipment (DME). The manufacturer would receive HCPCS code from CMS in order to qualify for this type of reimbursement.

The product needs to be listed in a pricing compendia so that the provider system can pull the information into their EHR. In this scenario, the software comes with hardware so it is usually on a different file than the drug like file. The manufacturer also needs to work with the provider system to select their product to pull from compendia listing to the EHR. Educating the individual clinicians is also important so that they can train the prescribers on how to prescribe the product.

The manufacturer needs to contract with the health plan and the health plan would determine the coverage policy as a medical benefit.

Finally, the manufacturer needs to contract with a third party intermediary or a licensed DME distributor in each state that they want to distribute their product in. Alternatively, the manufacturer also may become their own license DME distributor.

Once the payor decides to cover the product, the file is uploaded to the intermediary, the file gets downloaded to the EHR, and the prescribing clinician is able to search for the product. Since it is a medical benefit they will not be able to see if there is coverage so the clinician can still e-prescribe,send a fax, or order on a manufacturer portal based on instruction from the manufacturer. After the product is prescribed the intermediary or DME distributor handles all of the manual claims process. They would also be the entity to bill the patient if there is a copay or a deductible.

Then the intermediary or DME distributor ships the device to the patient along with information about how to download the software. Included in this packaging is also return packaging for the product when they're finished using it. The patient then begins using the product, generating the clinical data.

Then the patient uses the product and generates clinical data. Patient services can be put into two categories:

» General questions are the responsibility of the product manufacturer

» Specific questions related to a patient's personal health are the responsibility of the prescribing clinician

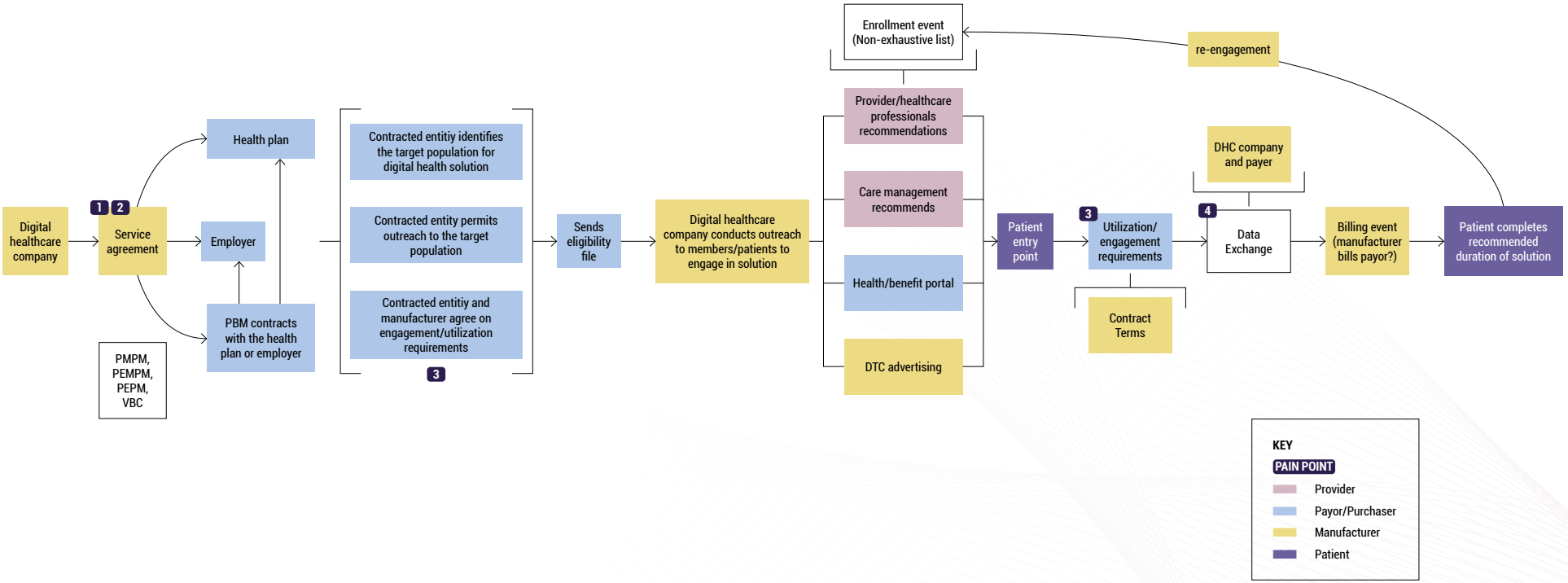
When the product term has ended, the patient returns the device using the packaging that was shipped out with the original shipment.

Prescription DTx Recommendations

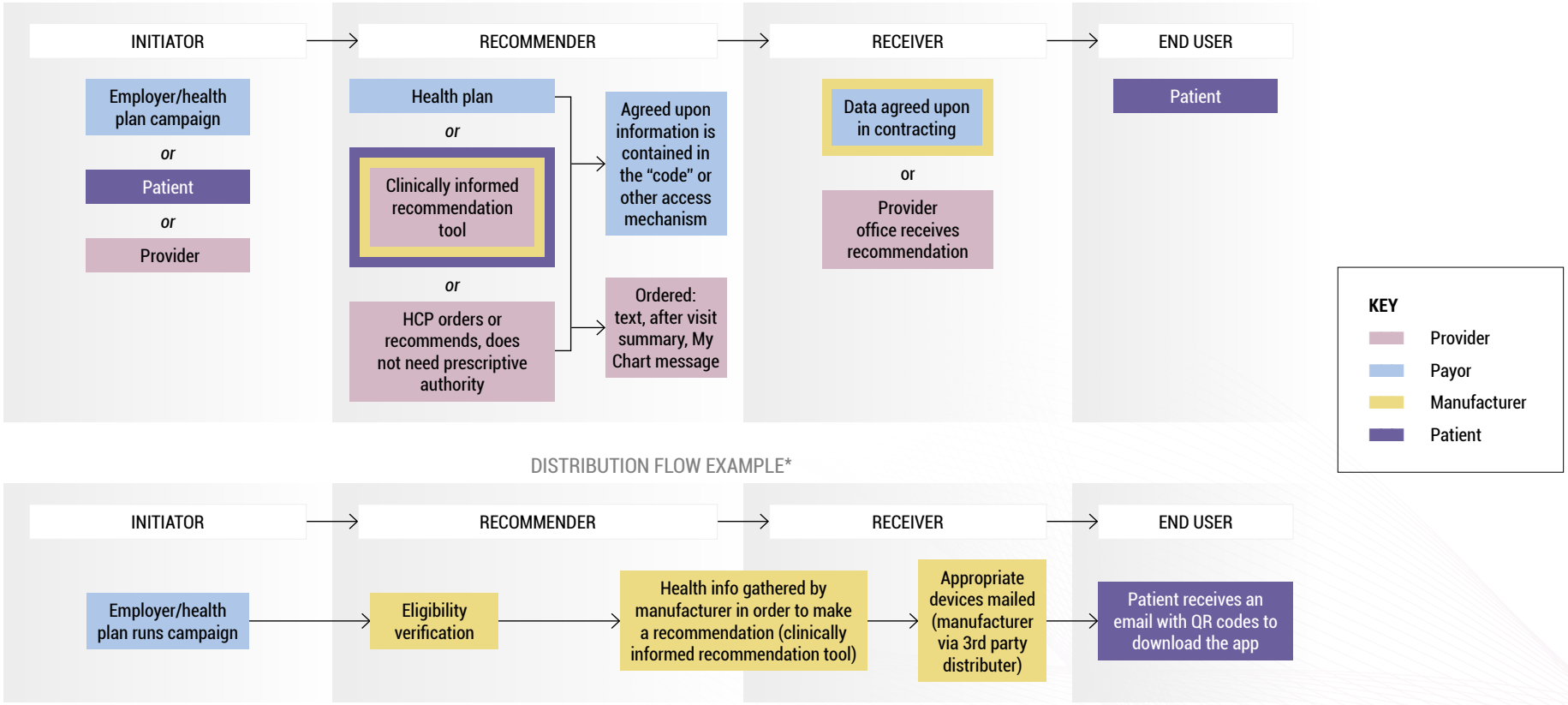
Pain Point	Considerations	Recommendations
1 The scope of professionals who are involved is not clearly defined	» What scope of professionals can order? This varies by state, varies by submission (label) to FDA » What scope of professionals can sign? » What scope of professionals can release/fulfill? » 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?	Collaborate with provider organizations to understand scope of practices by state
2 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 Task Group to work with state Medicaid programs because of their flexibility outside of federal legislation » DTA Policy Task Group to work with CMS and AMA to develop new product and service codes
3 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	Advocate for automated medical benefit claims process in partnership with other organizations
4 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	Work with health systems to add this functionality to their IT platforms

Non-Prescription Workflows

Non-Prescription DTx Integration & Workflow



Non-Prescription DTx Product Distribution Workflow



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

Non-prescription digital therapeutics emphasize accessibility, user engagement, and continuous improvement. By inclusion in employer benefit and health plan digital platforms, these therapeutics can provide effective and personalized health interventions without the need for a prescription, making them a valuable tool in the broader landscape of digital healthcare. This approach not only empowers users to take control of their health but also facilitates widespread adoption and scalability of digital health solutions.

Commentary on Non-Prescription Digital Therapeutic Distribution Workflow

When a vendor approaches an employer with a non-prescription digital therapeutic product designed to provide clinical services for employees, the process typically unfolds as follows:

1. **Eligibility File:** The first step involves determining an agreed upon population that the solution targets and obtaining an eligibility file to identify which employees are covered by the employer's health plan. This file commonly is generated by the employer then sent back to the vendor or the company providing the clinical service. Alternatively, the file may come from a Pharmacy Benefit Manager (PBM) that the employer uses. This file is often updated and sent on a weekly or monthly basis.

2. **Service Billing:** The vendor captures data on the number of services provided, such as coaching sessions or other clinical interactions. This data is compiled into a report, which is then billed to the employer on a set schedule, such as quarterly, as specified in the contract.

3. **Prior Authorization Integration:** Another emerging model integrates digital therapeutics into the prior authorization (PA) process. In this model, if a DTx product requires prior authorization, the claim can be directed to the digital health company during the PA process. This ensures that eligible members are engaged with the digital therapeutic solution at the appropriate decision point.

4. **Claims Data Utilization:** Additionally, claims data can be used to identify members with specific conditions, such as diabetes, based on their prescription history. This data helps target the digital therapeutic services to those who will benefit most.

Additional Considerations:

Healthcare Provider Recommendations: A different use case involves digital therapeutics being recommended directly by healthcare providers during clinic visits. This pathway relies on the clinical judgment and recommendation of the healthcare provider and can intersect with the member's benefit package.

Pathways:

- Digital therapeutics can be deployed based on the specific use case.
- Employer-based
- PA integration
- Provider recommendations
- While these pathways can be distinct, they often intersect depending on the individual's benefit package. Understanding and delineating these intersections can help streamline the deployment process and improve coordination between stakeholders.

Example of Eligibility in a Non-Prescription DTx Workflow

Eligibility in a non-prescription digital therapeutic (DTx) workflow can be divided into two main categories: Operational Eligibility and Clinical Eligibility.

Operational Eligibility:

1. **Plan Membership:** Verify if the member is currently covered by the PBM or health plan. This means confirming that the member is still employed with the employer that will cover the cost of the DTx.

2. **Prior Authorization:** Assess if prior authorization is required for the member to access the DTx. This operational check ensures that all necessary approvals are in place before the DTx is provided.

3. **Self-Attestation:** In some cases, members may attest to their own eligibility. This could be part of a patient education employer campaign and may preclude clinical eligibility, the member may not have either the diagnostic coding or claims history that would designate them for use.

Clinical Eligibility:

1. **Claims History:** Determine if the member has a diagnosis that makes them eligible for the DTx. This can be done by reviewing claims history to see if the member has been diagnosed with a relevant condition, such as diabetes, or has previously filed a claim for a related medication.

2. **Diagnostic Criteria:** Establish clinical criteria that the member must meet to be eligible for the DTx. These criteria can include specific diagnoses, treatment history, or other medical indicators that align with the intended use of the DTx.

By categorizing eligibility into operational and clinical components, we can streamline the workflow for non-prescription digital therapeutics, ensuring that only eligible members receive the appropriate therapeutic interventions.

Non-Prescription Recommendations

Pain Point	Update	Recommendations
1 Manufacturers are not easily able to identify the key decision maker in payor organization.	Manufacturers can identify the right decision makers within a payor organization by first establishing personas that represent key stakeholders such as clinical, economic, and data security decision makers. Educating both internal teams and payor members about these personas is crucial to understanding their specific needs and expectations. Additionally, manufacturers should meet the data requirements relevant to each persona to build trust and ensure their products align with the decision makers' priorities.	» Establish personas inside payor organizations. » Educating members and manufacturers about these personas » Meeting expected data requirements for identified personas ie clinical, economic and data security decision makers
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. » Allow payor to react to the contract timeline and process, adjusting based on their internal needs » 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 DTx 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 Integration with other payor solutions.	Does the new data generated and captured by the DTx solution aid with payor needs—whether that information is integrated in care management, supplied to providers' EHR, etc. Can the DTx solution synergize with payors current efforts of care gap closure?	Define feedback loop in conjunction with prescription workflow group.

Introduction to a Framework for Consistent Enrollment

In our previous report, we identified a pain point related to inconsistent enrollment for non-prescription DTx enrollment. A framework to address this pain point has been developed and validated by our multi-stakeholder group.

Ensuring consistent enrollment in non-prescription platforms requires a thoughtful, structured approach.The framework for consistent patient enrollment begins with aligning key stakeholders, including health plans, employers, and DTx manufacturers, to ensure a unified vision and shared goals. Clear objectives and collaborative planning among these parties set the foundation for a successful strategy. Identifying the target population is crucial, and leveraging data-driven insights—such as claims data and health risk assessments—helps pinpoint individuals who will benefit most from the DTx. Defining eligibility criteria and personalizing outreach efforts enhance engagement and relevance. A coordinated promotion strategy, featuring unified messaging and co-branded marketing materials, ensures effective communication of the DTx benefits, while educational initiatives like informational sessions and webinars build interest and understanding. Simplifying the enrollment process, offering incentives, and providing dedicated support channels help facilitate user adoption. Maintaining engagement through regular communication, progress tracking, and a feedback loop is key to sustaining usage and adherence. Finally, evaluating the success of the enrollment event through post-event analysis and iterative improvements ensures that the framework remains effective and adaptable, ultimately enhancing patient outcomes and the success of the DTx solution.

Framework to Improve Consistency in Enrollment for Non-Prescription Digital Therapeutics (DTx)

A. Stakeholder Alignment	B. Target Population Identification	C. Joint Promotion Strategy
» **Identify Key Stakeholders:** Involve the health plan, employer, and DTx manufacturer early in the planning process to ensure everyone is on the same page regarding goals and expectations. » **Set Clear Objectives:** Align on shared goals for the enrollment event, such as target population, expected uptake, and key performance indicators (KPIs). » **Collaborative Planning:** Develop a joint strategy that outlines each stakeholder's role and responsibilities in promoting and enrolling patients in the DTx solution.	» **Data-Driven Insights:** Use claims data, health risk assessments, and other analytics to identify the target population most likely to benefit from the non-prescription DTx. » **Eligibility Criteria:** Clearly define the eligibility criteria for enrollment, ensuring that both operational and clinical criteria are met. » **Personalized Outreach:** Tailor communication to the identified population segments to increase relevance and engagement.	» **Unified Messaging:** Create a consistent message that can be used across all promotional channels (email, social media, in-app notifications, etc.) to ensure clear communication of the DTx benefits. » **Co-Branded Campaign:** Develop co-branded marketing materials featuring the health plan, employer, and manufacturer to enhance credibility and trust. » **Employee and Member Education:** Offer informational sessions, webinars, or workshops to educate the target population about the benefits and usage of the non-prescription DTx.
D. Enrollment Support Mechanisms	**E. Ongoing Engagement and Monitoring**	**F. Evaluation and Iteration**
» **Simplified Enrollment Process:** Ensure the enrollment process is user-friendly and accessible across various platforms (mobile, desktop, in-person). » **Incentives and Motivators:** Consider offering incentives, such as wellness points, discounts, or rewards, to encourage participation. » **Dedicated Support Channels:** Provide a dedicated helpline or chat support for potential enrollees who need assistance or have questions about the DTx.	» **Continuous Communication:** Maintain regular touchpoints with enrolled patients to encourage ongoing use and adherence to the DTx solution. » **Progress Tracking:** Monitor enrollment rates and user engagement, using dashboards and reports to track progress against KPIs. » **Feedback Loop:** Collect feedback from users and stakeholders to identify areas for improvement and adjust strategies as needed.	» **Post-Event Analysis:** Conduct a thorough analysis of the enrollment event, assessing what worked well and what didn't. » **Lessons Learned:** Document key takeaways and share them with all stakeholders to refine future enrollment strategies. » **Iterative Improvements:** Use the insights gained to make continuous improvements to the enrollment framework, ensuring consistency and success in future initiatives.

Closing Statement

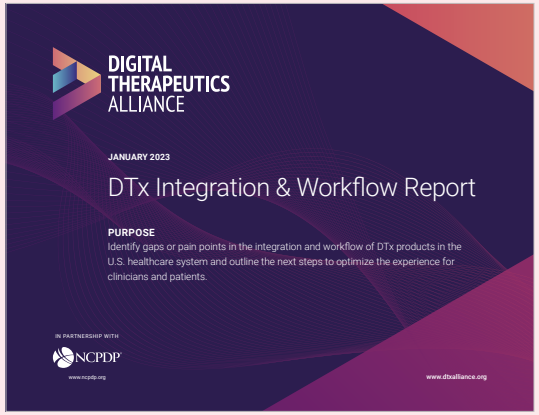
In conclusion, both prescription and non-prescription digital therapeutics (DTx) offer significant potential to enhance healthcare accessibility, improve patient engagement, and deliver personalized health interventions. Non-prescription DTx, in particular, expand access by utilizing pathways such as employer benefit programs, prior authorization integration, and healthcare provider recommendations, empowering individuals to take control of their health. Prescription digital therapeutics integrate into the healthcare system through established reimbursement pathways, including pharmacy and medical benefits, providing patients with clinically validated interventions.

As we refine workflows and delineate clinical and operational eligibility, it is crucial to ensure effective, targeted deployment and broader audience reach.

DTA remains proud of its members and the entire healthcare ecosystem for addressing pain points and driving innovations that make healthcare more accessible and higher quality for patients and their families. We will continue working collaboratively to tackle challenges that hinder positive experiences for patients, payors, and providers, ensuring the widespread adoption and scalability of transformative digital health solutions to improve population health outcomes.

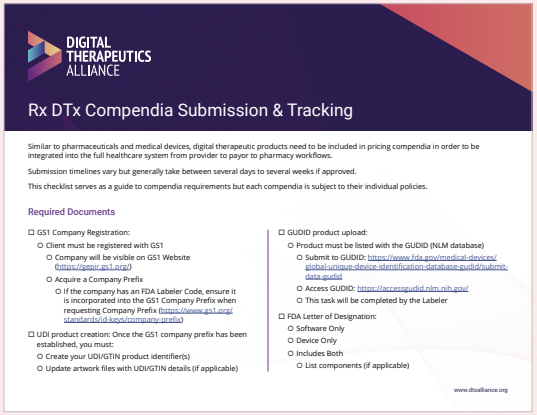
If you have additional questions or would like to learn more about the workflow and how to address the pain points, please contact us at info@dtxalliance.org.

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

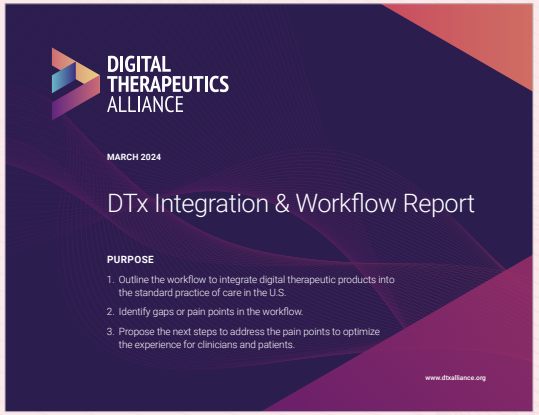


U.S. DTx Workflow & Integration Report
(January 2023)

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



Rx DTx Compendia Submission & Tracking
(August 2023)



U.S. DTx Integration & Workflow Report
(March 2024)

Resources

Rx DTx Compendia Submission & Tracking

Similar to pharmaceuticals and medical devices, digital therapeutic products need to be included in pricing compendia in order to be integrated into the full healthcare system from provider to payor to pharmacy workflows.

Submission timelines vary but generally take between several days to several weeks if approved.

This checklist serves as a guide to compendia requirements but each compendia is subject to their individual policies.

Required Documents

- ☐ GS1 Company Registration:
  - ○ Client must be registered with GS1
    - ○ Company will be visible on GS1 Website (https://gepir.gs1.org/)
    - ○ Acquire a Company Prefix
      - ○ If the company has an FDA Labeler Code, ensure it is incorporated into the GS1 Company Prefix when requesting Company Prefix (https://www.gs1.org/standards/id-keys/company-prefix)
- ☐ UDI product creation: Once the GS1 company prefix has been established, you must:
  - ○ Create your UDI/GTIN product identifier(s)
  - ○ Update artwork files with UDI/GTIN details (if applicable)
- ☐ GUDID product upload:
  - ○ Product must be listed with the GUDID (NLM database)
    - ○ Submit to GUDID: https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/submit-data-gudid
    - ○ Access GUDID: https://accessgudid.nlm.nih.gov/
    - ○ This task will be completed by the Labeler
- ☐ FDA Letter of Designation:
  - ○ Software Only
  - ○ Device Only
  - ○ Includes Both
    - ○ List components (if applicable)

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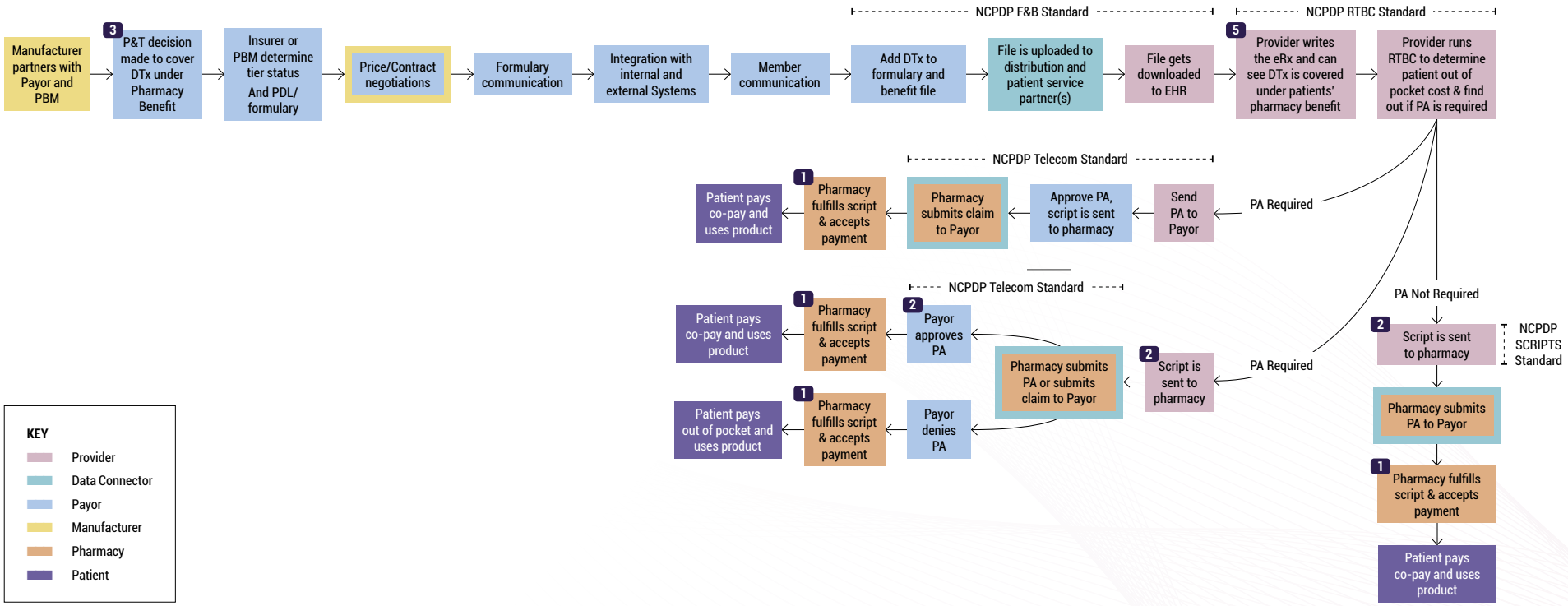
- ☐ Product Labeling:
  - ○ Brand Name
  - ○ Label Name (Product Name & Attributes)
  - ○ Barcode details and image(s)
    - ○ GTIN12
    - ○ GTIN14
    - ○ UDI
- ☐ Product Information:
  - ○ Operating system: iOS, android, or both
  - ○ Instruction for use (IFU)
  - ○ Clinical indication information (if applicable)
    - ○ Age range
    - ○ Duration of therapy
  - ○ Flyers/posters
  - ○ Users manual
  - ○ Image of product
  - ○ Identify the intended use (for classification purposes)
  - ○ Identify all Product Codes/SKUs
  - ○ Identify if Prescription Use Only (Rx or OTC)
  - ○ Pricing Information Required (Price Type to be submitted)
  - ○ Launch Date
- ☐ Authorized Distributors:
  - ○ Is Pharmacy involved (adjudication/processing)?
  - ○ Limited Distribution Pharmacy? (y/n)
- ☐ Submission Form (sample):
  - ○ Company Name
  - ○ Contact Name
  - ○ Contact Telephone Number
  - ○ Contact E-mail
  - ○ Product Code ID
    - ○ GTIN/UDI/UPC Number
    - ○ NHRIC (if applicable)
  - ○ Product Name
  - ○ Package Size
  - ○ Dosage Form
    - ○ Application
    - ○ VR Headset
    - ○ Kit
    - ○ Other
  - ○ Rx or OTC
  - ○ Wholesale Acquisition Cost
  - ○ Direct Price
  - ○ Suggested Average Wholesale Price
  - ○ Effective Date
  - ○ Product Physical Description if not provided in package insert or label (if applicable)

Version Tracking: *Compendia must be notified when an update is significant enough to require a change in UDI. It is at the discretion of each compendia, their editorial policy and ability as to whether products can be linked.*

Pharmacy Benefit

Pharmacy Benefit DTx Integration & Workflow



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:

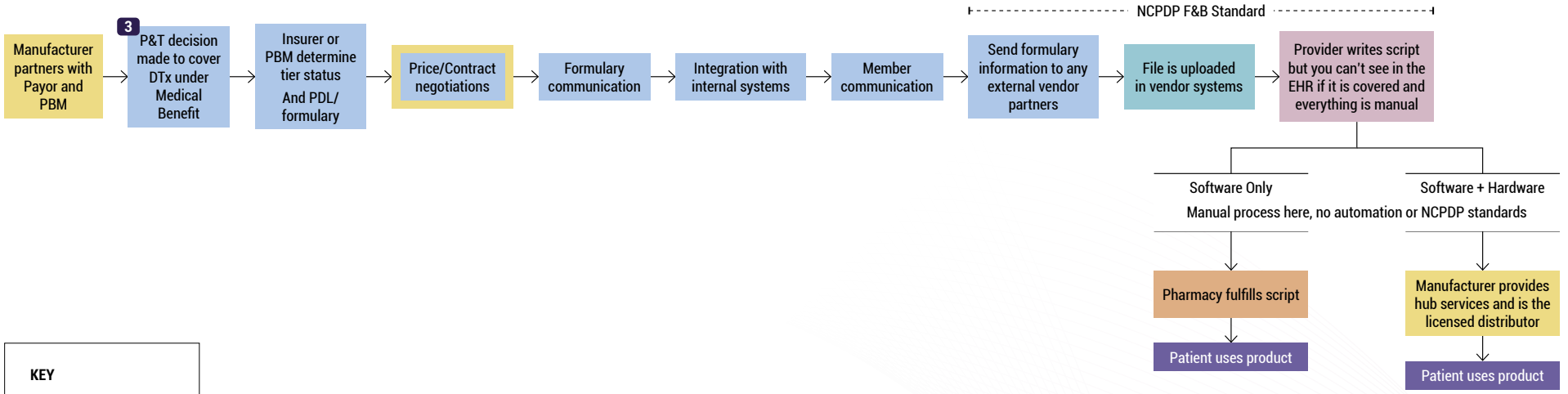
» Stakeholder Input: Gather feedback from healthcare providers, pharmacists, and plan members to improve the process and address any concerns or issues

Review and Updates:

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

Medical Benefit

Medical Benefit DTx Integration & Workflow



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

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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