Driving Health Equity through Technology & Service Innovation

July 14, 2021

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Disclosures

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Objectives

Objective 1: Describe market failures and opportunities for innovation serving Medicare and Medicaid dual-eligible individuals

Objective 2: Identify new approaches to benefit coverage determination for emerging technology

Objective 3: Review trends and future directions in telehealth coverage and discuss supporting evidence

Objective 4: Recognize the foundational elements that are necessary to shift to value-based payments

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Investment thesis

- Dollar flows rather than good will are drivers of societal change
- Investing in bottom of pyramid will yield greater than average long-term internal rate of return (IRR)
- Stellar, diverse founders will create competitive advantages (80% consideration)
- Large, underserved total addressable markets (TAM) primarily among public payer supply chain frictions (20% consideration)
- Primary peer-reviewed research will differentiate signal from noise

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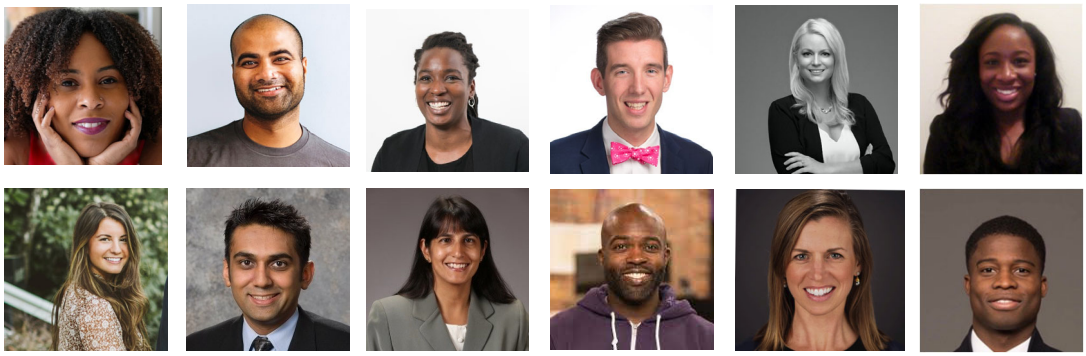
Some of our founders



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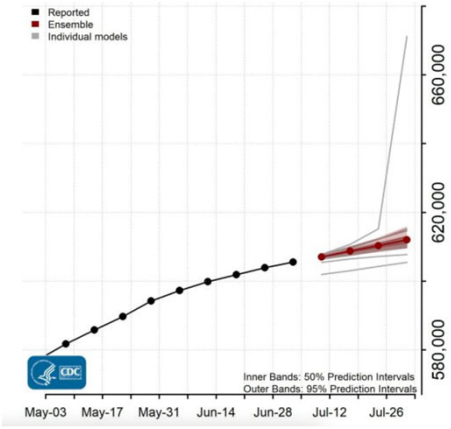
COVID19 deaths have surpassed 600,000



Source: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html

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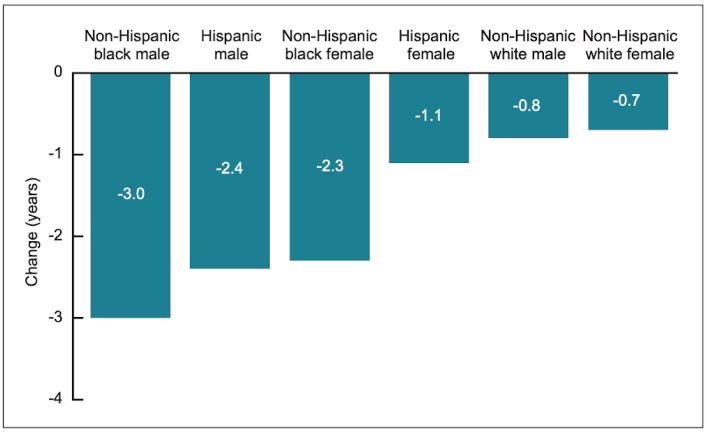
Profound growth in life-expectancy disparities



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data from January 2020 through June 2020.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Source: https://www.cdc.gov/nchs/data/vsrr/VSRR10-508.pdf

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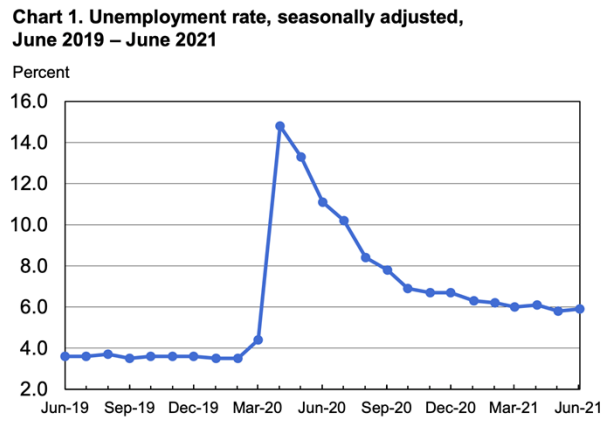
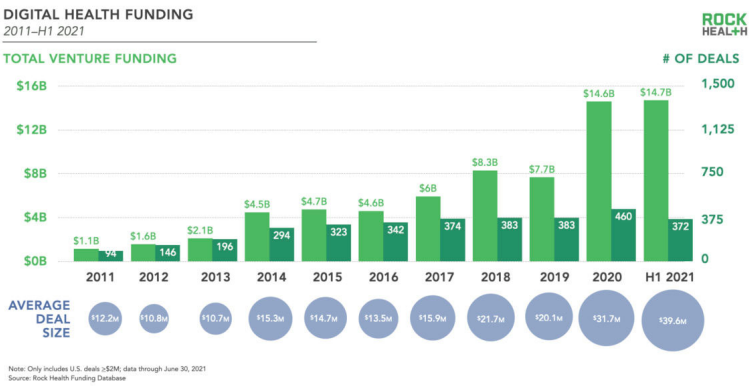
US unemployment rate still 6%



Source: https://www.bls.gov/news.release/pdf/empsit.pdf

Record breaking H1 2021 for digital health funding



Source: https://rockhealth.com/reports/h1-2021-digital-health-funding-another-blockbuster-year-in-six-months/

Methods

1. Describe the context of dual eligible participants in California
2. Characterize the barriers to addressing duals' health needs as identified in the literature and in interviews with experts and key stakeholders in the duals space
3. Characterize new technologies applicable to dual eligible care
4. Apply our review of existing technologies to the gaps in dual eligible care
5. Explain future directions in technological investment to better serve dual eligible people

Source: socialinnovationventures.co/research

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Context for duals

60% percent of dual eligible patients ("duals") have multiple chronic health problems, and 41% have at least one mental health diagnosis.[3]

Roughly **half** of dual beneficiaries are eligible for the Medicare portion of their coverage based on disability and half based on age being 65 or older.[3]

20% of Medicare beneficiaries are dual eligible and they make up 33% of the total healthcare costs, while 15% of Medicaid recipients are dual eligible and they make up 34% of the total cost.[4]

Duals are **4x** more likely to get COVID-19 as non-duals and much more likely to be hospitalized.[5] The vulnerability of this population has been exacerbated by the COVID-19 pandemic.

Source: socialinnovationventures.co/research

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Expert interviews to characterize pain points

Source: socialinnovationventures.co/research

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Expert interviews to characterize pain points

1. Care coordination
2. Data collection and sharing
3. Culturally sensitive enrollment and engagement
4. Home and community based services

Source: socialinnovationventures.co/research

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Characterize new tech applicable to duals: evaluation framework

Funding Round was based on ordinal criteria. Candidate technologies needed to have at least Series A funding, with the exception of ad hoc inclusion per the suggestion of the research team. Companies with Series D funding or higher were included in the analysis but they were not the focus of this framework. Companies that were acquired were excluded from this analysis.

Company Serving Duals was a designation based on whether duals or the duals supply chain were the primary or secondary customer segment, or whether they were not one of the company's customer segments.

The **Level of Evidence** category had six ordinal categories including: no evidence, gray literature including white papers, based on evidence-based practice, single peer-reviewed study (excluding randomized controlled trials), multiple peer-reviewed studies (excluding randomized controlled trials), and at least one randomized controlled trial. The company website needed to make explicit reference to studies in one of these categories in order to have that level of evidence designated in the Duals Innovation Inventory.

The **End-User** category had three subcategories (primary, secondary, and tertiary) to account for some companies having multiple end-user types. Each end-user type had 6 nominal categories including: Consumer, Health plan, Medical provider, Non-medical provider, Pharmacy Benefit Manager (PBM), and Employer.

The **Financial Customer** category had three subcategories (primary, secondary, and tertiary) to account for some companies having multiple financial customers. Each financial customer type had eleven nominal categories including: Consumer, Medicare Advantage (MA) plan (ie dSNP), Medicaid Managed Care Organization (MCO, ie mLTSS), Individual/Exchange plan, Commercial plan, Medical provider, Pharmacy Benefit Manager (PBM), Employer, Non-medical provider, State government (ie State Medicaid Program), and the federal government.

The **Technology Type** category had three subcategories (primary, secondary, and tertiary) to account for some companies' technology fitting into multiple technology categories. Each technology type had eight nominal categories including Business Process as a Service (BPaaS), Consumer, Digital, Provider/Enterprise, Tech Enabled Services, Telehealth, and Other. There were 49 additional sub-categories to further refine the technology type.

Source: Duals Tech Inventory: https://bit.ly/2O5yHqS from socialinnovationventures.co/research

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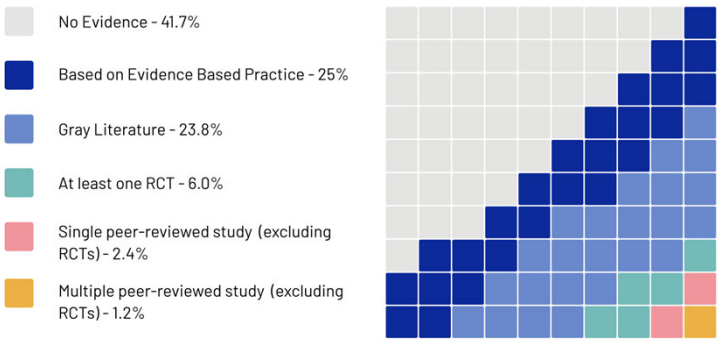
Characterize new tech applicable to duals: level of evidence



Vast majority (>90%) of companies have not tested their product or service in any peer-reviewed study.

Source: socialinnovationventures.co/research

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Consistent with prior studies

Figure 2. Number of Technologies by Level of Evidence

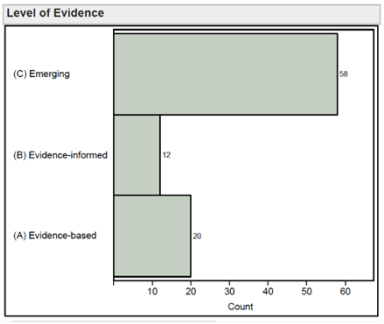
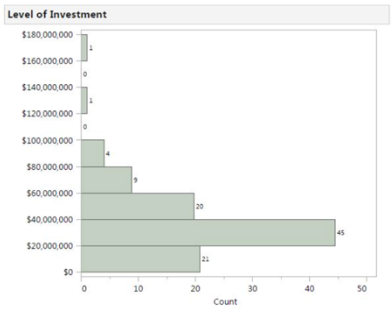


Figure 5. Level of Investment Funding in Technologies



Investment in digital health had no significant correlation with the Level of Evidence.

Source: ihi.org/resources/Pages/Publications/AFrameworkforSelectingDigitalHealthTechnology.aspx

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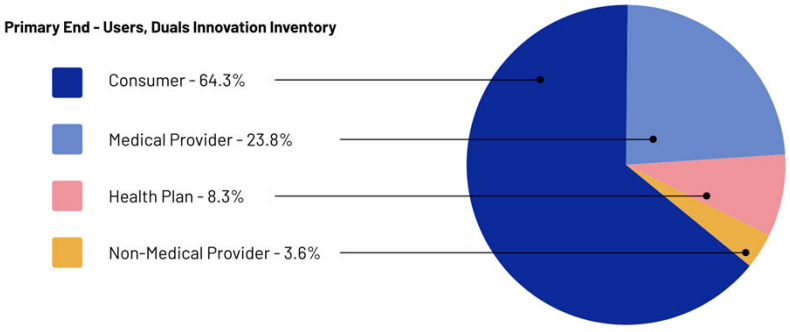
Characterize new tech applicable to duals: end-users



Disconnect between the target-end user and access to technology is an important market failure that needs remediation

Source: socialinnovationventures.co/research

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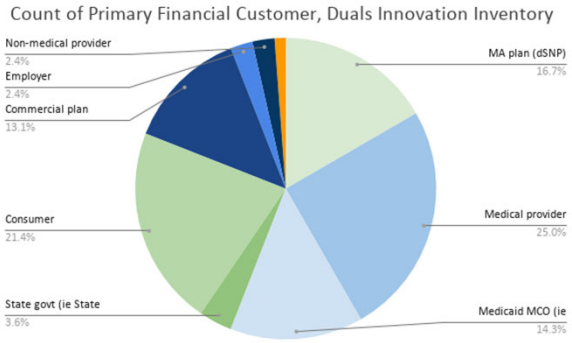
Characterize new tech applicable to duals: financial customer



Many companies attempting to create technology for duals may not understand their customer's limited purchasing power. Lack of empathy between innovators and investors and the duals they claim to be serving.

Source: socialinnovationventures.co/research

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Apply technology scan to duals market gaps: care coordination

AllyAlign Health
CITYBLOCK
bright HEALTH
Quartet
SOMATUS
REVOLUTIONIZING KIDNEY CARE
Zing HEALTH
Clover Health
inquisithealth
Cricket Health

Source: socialinnovationventures.co/research

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Increased coordination & engagement through concordant care with peers reduced HgA1c 1.71% (*P*<.01) (Inquisit Health)

Table 2.
Categories and distribution of social determinants of health issues during mentoring sessions

Total number of issues addressed = 4192	Diabetes or lifestyle behavior issue addressed (n = 3557)	Social determinants issue addressed (n = 451)	Issues escalated to health system for additional intervention (n = 184)
Diabetes principles	717	–	–
Diet	741	40	–
Medications	290	75	45
Blood sugar monitoring	291	58	41
Appointments	642	103	63
Loss of insurance coverage	2	41	7
Mental health/stress	368	95	15
Exercise	465	–	–
Other health conditions	40	–	–
Housing	–	31	7
Transportation	–		6
Alcohol, smoking, substance use	1	8	–

Table 3.
Improvement in A1c (Control or Measurement) among participants

	N	A1c change
Primary cohort: Mean change in HbA1c	179	−1.71
Secondary Analyses		
Primary cohort: Proportion HbA1c < 9% at follow-up	179	42%
Primary cohort + patients with outdated baseline HbA1c	300	−1.51
Proportion of participants with no/outdated baseline HbA1c values receiving follow-up HbA1c after coaching	244	44%

Source: Courtney R Lyles, Urmimala Sarkar, Urvashi Patel, Sarah Lisker, Allison Stark, Vanessa Guzman, Ashwin Patel, Real-world insights from launching remote peer-to-peer mentoring in a safety net healthcare delivery setting, *Journal of the American Medical Informatics Association*, Volume 28, Issue 2, February 2021, Pages 365–370,.

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Apply technology scan to duals market gaps: data collection & sharing

Healthify
FIGmd
PATIENTPING
SOCIALLYDETERMINED
UNITE US
VALIDIC
xealth
verato

Source: socialinnovationventures.co/research

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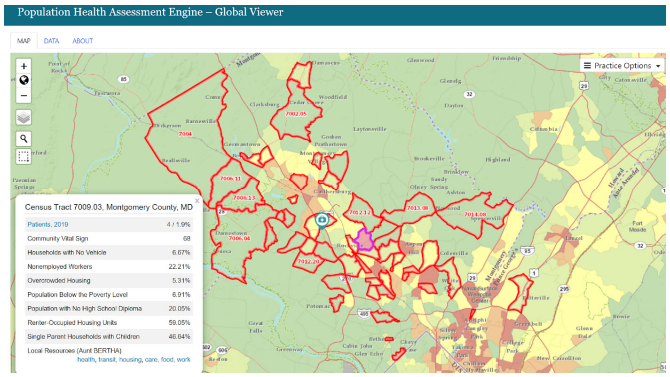
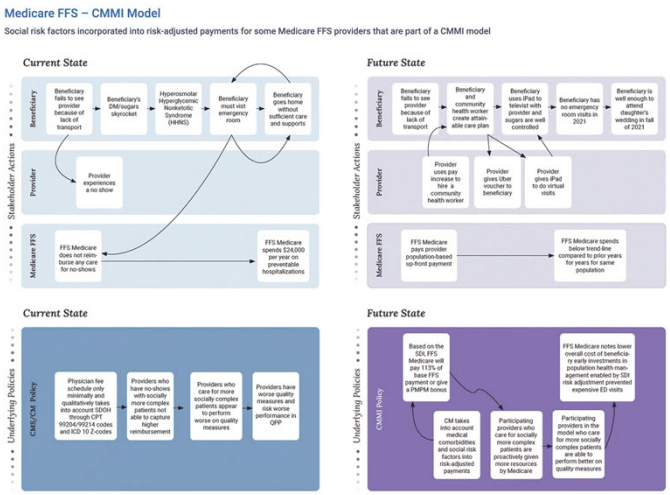
Small-area deprivation indices inform population health management



Source: professionalismandvalue.org/designing-future-state-to-account-for-social-risk-in-cms-payments/

Incorporating SDI into payment risk-adjustment



Source: https://www.healthaffairs.org/do/10.1377/hblog20210526.933567/full/

Apply technology scan to duals market gaps: home and community based services (HCBS)

edenbridgehealth · CONNECT Life. Connected. · papa · roundtrip · healthcare Vesta · Welbe Health · Wider Circle

Source: socialinnovationventures.co/research

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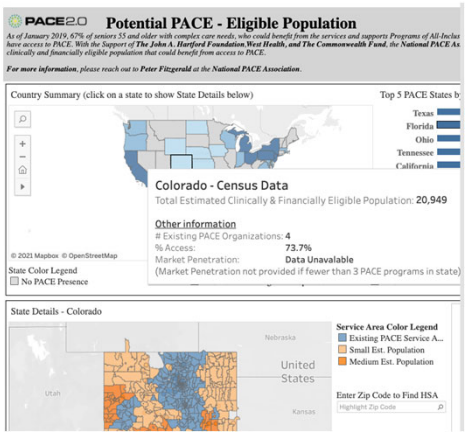
PACE Growth and Investment Summit: Oct 19



Source: npaonline.org/member-resources/strategic-initiatives/pace2-0/interactive-map-potential-pace-eligible-population

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Apply technology scan to duals market gaps: enrollment & engagement

Source: socialinnovationventures.co/research

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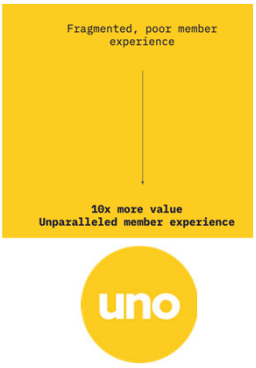
Key state and federal programs eligible to low income Medicare Advantage members by FPL

Income bracket	Full Duals (100%)	Partial Duals (135%)	LIS Levels (150%)	Non duals (Up to 400%)
Medicaid	✔			
MSP (QMB)	✔ (QMB)	✔ (SLMB / QDWI)	✔ (QI)	
LIS Levels 1, 2, 3	✔			
LIS Level 4		✔100%	✔25/50/75%	
SNAP	✔	✔	✔	
State Rx program		✔	✔	✔
LIHEAP	✔	✔	✔	
Lifeline	✔	✔	✔	✔
Total member impact	**$13K**	**$7K**	**$5K**	**$1K**



Source: https://www.unohealth.com/

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(lack of) Coverage and payment of evidence-based prescription digital therapeutics is an ethical issue

- Ethical argument against coverage and payment
  - Non-maleficence (do no harm) – although limited, research suggests digital therapeutics are safe
  - Efficiency – value based payment mitigates this risk
- Ethical argument for coverage and payment
  - Beneficence (duty to produce benefit) – strong evidence for positive outcomes for certain tech
  - Justice (treat patients fairly and equitably) – high risk for inequitable access with cash pay

Source: Summers J. Principles of Healthcare Ethics. Ch 2. 2009. Accessed via http://samples.jbpub.com/9781284124910/9781284124910_CH02_OnlineCat.pdf

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(lack of) Coverage and payment of evidence-based prescription digital therapeutics is an ethical issue

Clinical Indications

Medically Necessary:

Mobile-based health management applications are considered **medically necessary** when *all* of the following criteria in I and II have been met:

I. Criteria to evaluate the mobile software application (MSA):

A. The MSA has been approved or cleared by the Food and Drug Administration (FDA); **and**
B. There is credible scientific evidence which permits reasonable conclusions regarding the impact of the MSA on health outcomes; **and**
C. The MSA has been proven materially to improve the net health outcome or be as beneficial as any established alternative;

AND

II. Criteria to evaluate the appropriateness of the MSA for the individual:

A. The MSA has been prescribed by a healthcare practitioner; **and**
B. There is documentation supporting that the MSA was ordered for a covered purpose such as preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and in accordance with generally accepted standards of medical practice;* **and**
C. The requested MSA is not primarily for the convenience of the individual, prescribing clinician, caregiver, or other healthcare provider.

*Generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas, and any other relevant factors.

Not Medically Necessary:

Mobile-based health management applications are considered **not medically necessary** when the criteria above have not been met.

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(lack of) Coverage and payment of evidence-based prescription digital therapeutics is an ethical issue

Identification of new evidence		
Time frame for updating		
≤1 year	3	8.6
2-3 years	14	40.0
4-5 years	8	22.9
No specific time frame indicated	10	28.6

Waiting for medical societies to update clinical practice guidelines violates **beneficence** and **justice** principles with unethically long lead time (majority over 2 years)

Source: Vernooij, R.W., Sanabria, A.J., Solà, I. *et al.* Guidance for updating clinical practice guidelines: a systematic review of methodological handbooks. *Implementation Sci* **9,** 3 (2014).. Accessed via https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-9-3

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(lack of) Coverage and payment of evidence-based prescription digital therapeutics is an ethical issue

- Hayes – No Data
- ECRI – No Data
- UpToDate – No Data
- Policy Reporter – No results
- **Express Scripts Includes Propeller Health in Its First Formulary for Digital Health Solutions [Press Release] December 2019**

"Starting in January 2020, the Express Scripts Digital Health Formulary initially includes 15 solutions including remote monitoring services and digital therapeutics that aid in the management of eight of the country's most common chronic conditions: diabetes, prediabetes, hypertension, asthma, pulmonary disease, depression, anxiety and insomnia. The first selected solutions on the formulary include:

- Livongo, which will have preferred status on the formulary, for their diabetes, diabetes prevention and hypertension family of products
- Omada Health digital care programs for diabetes, diabetes prevention and hypertension
- LifeScan OneTouch Reveal® Plus powered by Welldoc's BlueStar® platform for diabetes
- Learn to Live and SilverCloud Health digital mental health platforms for depression, anxiety and insomnia
- Propeller Health digital health programs for asthma and COPD

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Some outcomes data/Not FDA cleared
- Livongo, which will have preferred status on the formulary, for their diabetes, diabetes prevention and hypertension family of products

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Reasonable outcomes data/FDA cleared
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Reasonable outcomes data/FDA cleared
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(lack of) Coverage and payment of evidence-based prescription digital therapeutics is an ethical issue

Letting salesmanship and shiny-object-syndrome rather than science drive what makes it onto formularies violates **non-maleficence** and **justice** principles (as well as concept of futility).

Evidence synthesizers like Hayes and UptoDate being luddites violates **beneficence** and **justice** principles by perpetuating long lead times for updating medical standards

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Digital therapeutics & diagnostics have potential to close access gaps to effective & safe interventions

HealthAffairs

- Growing rigor and quality spurred by FDA evidence review process evolution
- Demand for socially-distanced clinical interventions during and beyond COVID19
- Transportation and other access issues impeding in-person care
- Polypharmacy and side-effects of molecule drugs
- Heightened consumer expectation of convenience and experience
- Digital exhaust creates opportunity to minimize fraud, waste, and abuse

Source: https://www.healthaffairs.org/do/10.1377/hblog20201029.537211/full/

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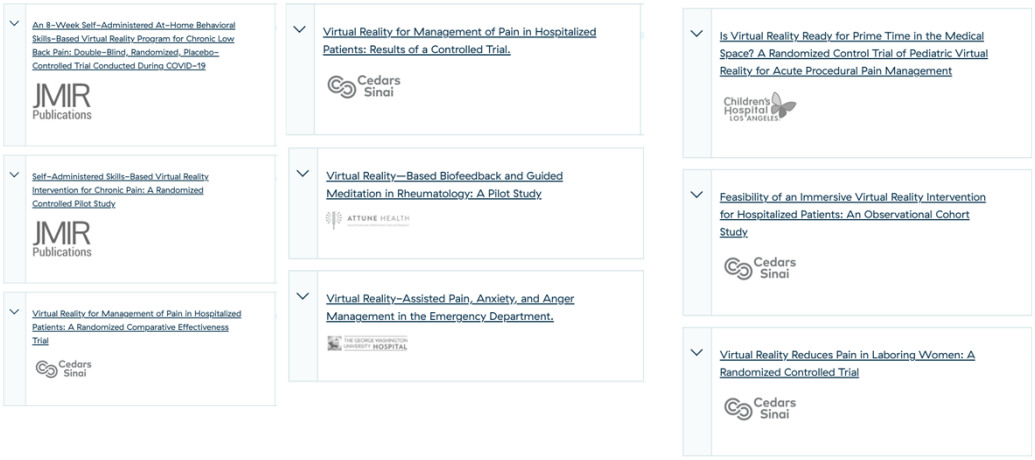
Sustained effect size for virtual reality treating pain (AppliedVR FDA breakthrough designated)



Source: appliedvr.io/research/

Improvement in ADHD symptoms in children (EndeavorRx FDA cleared)

Open label study in children with ADHD, both on and off medications: Published in npj Digital Medicine on March 26, 2021

Kollins, S.H., Childress, A, Heusser, AC and Lutz, J. (2021). Effectiveness of a digital therapeutic as adjunct to treatment with medication in pediatric ADHD. npj Digit. Med. 4, 58. https://doi.org/10.1038/s41746-021-00429-0

Pilot Study and three-years follow up study in SPD and co-occurring ADHD in children: Published in PLoS ONE on April 17, 2017 and PLoS ONE on February 4, 2021

Anguera JA, Brandes-Aitken AN, Antovich AD, Rolle CE, Desai SS, and Marco EJ. A pilot study to determine the feasibility of enhancing cognitive abilities in children with sensory processing dysfunction. PLoS One. 2017;12(4):1-19. doi:10.1371/journal.pone.

Jurigova, B. G., Gerdes, M. R., Anguera, J. A., & Marco, E. J. (2021). Sustained benefits of cognitive training in children with inattention, three-year follow-up. PLoS one, 16(2), e0246449.

Randomized controlled trial in ADHD in children: Published in Lancet Digital Health on February 24, 2020

Kollins, SH, DeLoss, DJ, Canadas, E, et al. A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomized controlled trial Lancet Digital Health 2020; 2(4): PE168-E178 doi: https://doi.org/10.1016/S2589-7500(20)30017-0

Open-label study in ADHD in children, with and without stimulant medication: Presented at the Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP), October 12-24, 2020

Kollins S.H., Heusser A., Lutz J. A Home-Based, Digital Treatment for Pediatric ADHD as Adjunct to Stimulant Medication: Insights on Repeat Administration and the Stability of Effects.

Childress, A.C., Lutz, J., Kollins, S.H. AKL-T01, a Digital Treatment for Pediatric ADHD as an Adjunct to Stimulant Medication: Response Rates with Repeat Administration.

Davis N., Lutz J., Kollins S.H. AKL-T01, a Home-Based Digital Intervention as an Adjunct to Stimulant Medication for Pediatric ADHD: Academic Performance and Relation to Objective Measures of Attention.

Multi-study analysis on moving objective measures of attention into normative ranges in ADHD with AKL-T01: Presented at Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP), October 12-24, 2020

Melmed R., Lutz J., Jina A. Improving Objective Measures of Attention in Test of Variables of Attention (TOVA) into Normative Ranges with AKL-T01, a Digital Treatment for Attention in Pediatric ADHD.

Pilot study in ASD and co-occurring ADHD in children: Published in Journal of Autism and Developmental Disorders on December 19, 2018

Yerys BE, Bertollo JR, Kenworthy L, et al. Brief Report: Pilot Study of a Novel Interactive Digital Treatment to Improve Cognitive Control in Children with Autism Spectrum Disorder and Co-occurring ADHD Symptoms. J Autism Dev Disord. 2019;49(4):1727-1737. doi:10.1007/s10803-018-3856-7

Proof of concept study in ADHD in children: Published in PLoS ONE on January 11, 2018

Davis, NO, Bower, J, and Kollins, SH. Proof-of-concept study of an at-home engaging, digital intervention for pediatric ADHD. PLoS One, 2018, 13(1): e0189749. https://doi.org/10.1371/journal.pone.0189748

Source: https://www.akiliinteractive.com/publications

Improvements in asthma and COPD outcomes (Propeller FDA cleared)

1. Kaye L, Gondalia R, Barrett MA, Williams M, Stempel DA. Concurrent improvement observed in patient-reported burden and sensor-collected medication use among patients enrolled in a COPD digital health program. Frontiers in Digital Health. 2021;3:27.
2. Jarrin R, Barrett MA, Kaye L, Sayiner S, von Leer A, Johns J, D'Andrea L, Nunez C, Ostrovsky A. Need for clarifying remote physiologic monitoring reimbursement during the COVID-19 pandemic: a respiratory disease case study. NPJ digital medicine. 2021 Mar 12;4(1):1-5.
3. Moore A, Preece A, Sharma R, Heaney LG, Costello RW, Wise RA, Ludwig-Sengpiel A, Mosnaim G, Rees J, Tomlinson R, Tal-Singer R. A randomized controlled trial of the effect of a connected inhaler system on medication adherence in uncontrolled asthmatic patients. European Respiratory Journal. 2021 Jan 1. (Link)
4. Anderson III WC, Gondalia R, De Keyser HE, Kaye L, Szefler SJ, Stempel DA. Digital assessment of medication utilization by age and diagnosis of asthma or COPD. The Journal of Allergy and Clinical Immunology: In Practice. 2020 Nov 16. (Link)
5. Mosnaim GS, Stempel DA, Gonzalez C, Adams B, Benlsrael-Olive N, Gondalia R, Kaye L, Shalowitz M, Szefler S. The Impact of Patient Self-Monitoring Via Electronic Medication Monitor and Mobile App Plus Remote Clinician Feedback on Adherence to Inhaled Corticosteroids: A Randomized Controlled Trial. The Journal of Allergy and Clinical Immunology: In Practice. 2020 Nov 16. (Link)
6. Kan K, Fierstein J, Boon K, Kanaley M, Zavos P, Volerman A, Vojta D, Gupta RS. Parental quality of life and self-efficacy in pediatric asthma. Journal of Asthma. 2020 Feb 25:1-8. (Link)
7. Kan K, Shaunfield S, Kanaley M, Chadha A, Boon K, Morales L, Davis MM, Vojta D, Gupta RS. Health provider perspectives of electronic medication monitoring in outpatient asthma care: a qualitative investigation using the consolidated framework for implementation research. Journal of Asthma. 2020 Nov 16:1-0. (Link)
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Source: propellerhealth.com/outcomes/

Equitable and timely diagnosis of autism (Cognoa FDA cleared)

Multi-modular AI Approach to Streamline Autism Diagnosis in Young Children

PUBLICATIONS TECHNICAL PAPERS

MARCH 19, 2020

Halim Abbas, Ford Garberson, Stuart Liu-Mayo, Eric Glover & Dennis P. Wall Scientific Reports volume 10, Article number: 501 Abstract Autism has become a pressing healthcare challenge. The instruments used to aid diagnosis are time and labor exper leading to long wait times for at-risk children. We present a multi-modular, machine learning-based assessment of autism cor

ASD symptoms in toddlers and preschoolers: An examination of sex differences

CLINICAL PAPERS PUBLICATIONS

NOVEMBER 26, 2019

Rosmary Ros-Demarize, Catherine Bradley, Stephen M. Kanne, Zachary Warren, Andrea Boan, Clara Lajonchere, Justine Park, I considerable work has documented higher prevalence rates of autism spectrum disorder (ASD) in boys, fewer studies have fo children at-risk for ASD. This study examined sex differences in ASD symptom domains and ASD screening outcomes...

In-Home Speech and Language Screening for Young Children: A Proof-of-Concept Study Using

CLINICAL PAPERS PUBLICATIONS

MAY 6, 2019

Du Y1,2, Abbas H2, Taraman S1,2,3, Segar S2, Bischoff N2. Author information 1University of California, Irvine, CA, USA.2Cogn Orange County, Orange, CA, USA. Abstract Early identification and intervention of speech and language delays in children con for school readiness and are protective against behavioral and mental health problems. Through collaboration between...

When Are We Sure? Predictors of Clinician Certainty in the Diagnosis of Autism Spectrum

CLINICAL PAPERS PUBLICATIONS

APRIL 1, 2019

Journal of Autism and Developmental Disorders. Access publication here.

Effect of Wearable Digital Intervention for Improving Socialization in Children With Autis Clinical Trial

PUBLICATIONS TECHNICAL PAPERS

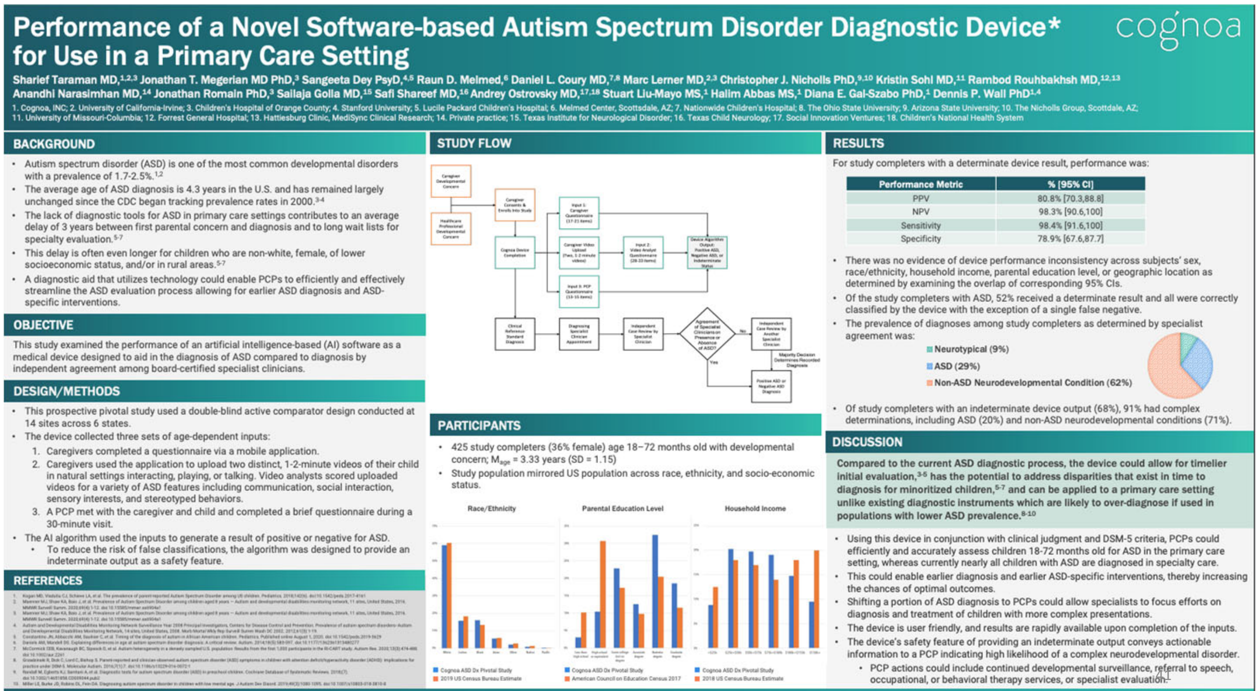
MARCH 25, 2019

JAMA Pediatr. 2019;173(5):446-454. doi:10.1001/jamapediatrics.2019.0285 Catalin Voss, MS1; Jessey Schwartz, BA2; Jen children with autism spectrum disorder, children treated at home with the wearable intervention showed a significant standard of care behavioral therapy. Read full publication here.

Mobile detection of autism through machine learning on home video: A development an

PUBLICATIONS TECHNICAL PAPERS

Source: cognoa.com/our-science/publications/



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Characteristics of optimal technology benefit coverage determination processes

1. Engage a broad array of stakeholders
2. Shift away from the state Medicaid agency solely bearing the burden of proof
3. Make coverage determinations transparent, systematic, and evidence-based
4. Ensure diverse makeup of committee making coverage determinations
5. Move toward digitized online submissions
6. Include a conflict of interest disclosure in the online submission
7. Standardize and make transparent evidence ratings
8. Ensure equity is a highly ranked variable
9. Make scores and thresholds for coverage transparent
10. Make easily available information on how state agency leaders implement decisions
11. Release clinical data on the impact of coverage decisions

Health Affairs

Source: https://www.healthaffairs.org/do/10.1377/hblog20201029.537211/full/

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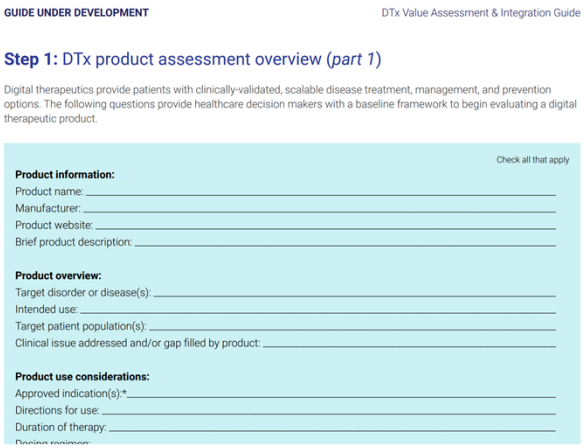
Benefit category choices for digital therapeutics

Benefit Category	Special Considerations	Candidate Digital Therapeutic
Pharmacy Benefit	Use of UDI code to adjudicate as a pharmacy benefit. Would need to be FDA cleared and require approval from CMCS to benefit the state from the Sect 1927k Medicaid Drug Rebate Program (MDRP). Incorporate into digital or standard pharmacy formulary with pharmacy benefit managers (PBMs).	Bluestar (Welldoc)
Pharmacy Benefit as "Other related item" for a drug	Use of a UDI code or HCPCS Level II code. 14 states have added continuous glucose monitors" to prescription drug lists (PDL). Submission to CMS should be as "other related charges" pharmacy dollars. Digital therapeutics put on PDL this way can get the rebate from the MDRP.	Propeller Health (ResMed)
Device, DME, or Testing	Use of a HCPCS Level II code. Major software updates should be covered as supplies. Routine updates should be considered normal/routine servicing of digital health technologies.	EaseVRx (AppliedVR)
Other Mandatory or Optional Medicaid Benefit Service	Use of CPT codes associated with provider services that are mandatory benefits like 96111 for Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) whereby a digital therapeutic supports a physician in their services.	Cognoa Diagnostic (Cognoa)

HealthAffairs

Source: https://www.healthaffairs.org/do/10.1377/hblog20201029.537211/full/

Study in progress: Mixed-method approach to evaluating development of DTx Value Assessment Guide



GUIDE UNDER DEVELOPMENT

DTx Value Assessment & Integration Guide

Step 1: DTx product assessment overview (*part 1*)

Digital therapeutics provide patients with clinically-validated, scalable disease treatment, management, and prevention options. The following questions provide healthcare decision makers with a baseline framework to begin evaluating a digital therapeutic product.

Check all that apply

Product information:
Product name: _____
Manufacturer: _____
Product website: _____
Brief product description: _____

Product overview:
Target disorder or disease(s): _____
Intended use: _____
Target patient population(s): _____
Clinical issue addressed and/or gap filled by product: _____

Product use considerations:
Approved indication(s):* _____
Directions for use: _____
Duration of therapy: _____
Dosing regimen: _____

Source: https://dtxalliance.org/wp-content/uploads/2021/06/HCDM-Feedback-DTx-Value-Assessment-Guide.pdf

Objectives

Objective 1: Describe market failures and opportunities for innovation serving Medicare and Medicaid dual-eligible individuals

Objective 2: Identify new approaches to benefit coverage determination for emerging technology

Objective 3: Review trends and future directions in telehealth coverage and discuss supporting evidence

Objective 4: Recognize the foundational elements that are necessary to shift to value-based payments

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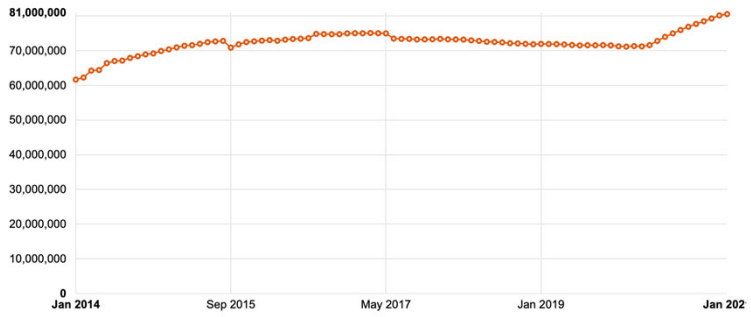
Medicaid enrollment increased 14% due to COVID19



Source: https://www.kff.org/health-reform/state-indicator/total-monthly-medicaid-and-chip-enrollment/

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Medicaid Medical Director Survey on Telehealth

- Survey distributed to MMDN members on January 5, 2021
- Survey questions derived from a review of 10 state medicaid programs bulletins on coding and coverage for telehealth services during the PHE
- ~5-7 min completion time
- 10% response rate
- Respondents were completely anonymous and confidential

Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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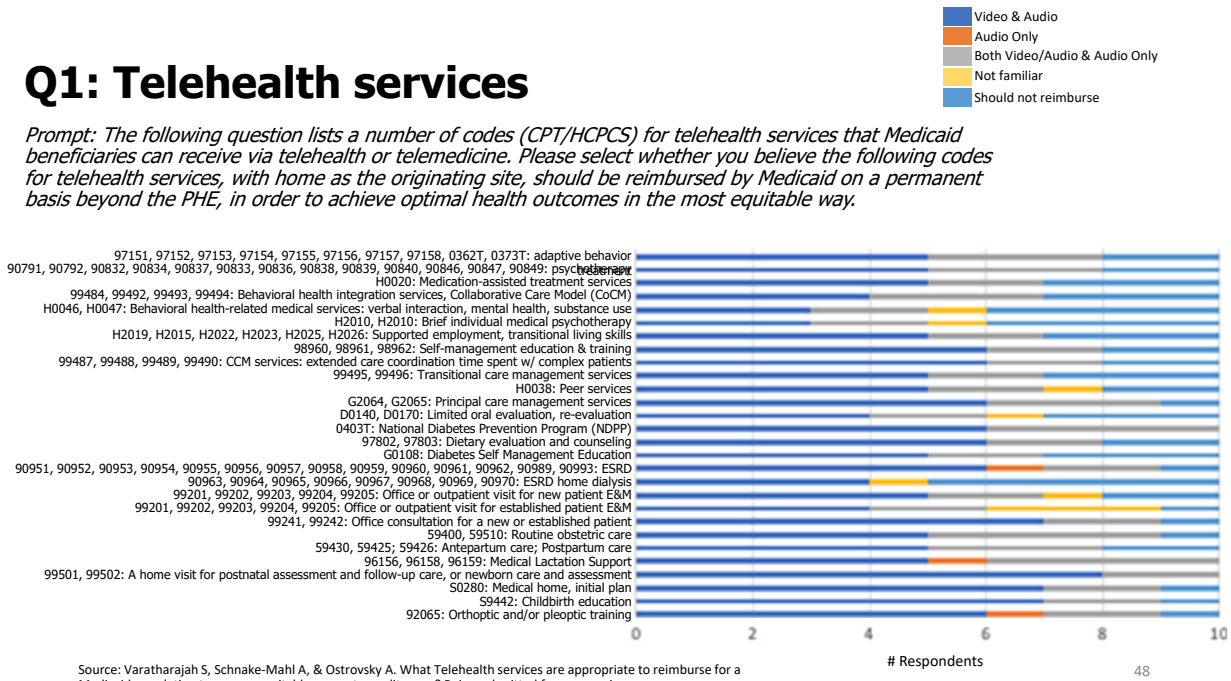
Q1: Telehealth services

Prompt: The following question lists a number of codes (CPT/HCPCS) for telehealth services that Medicaid beneficiaries can receive via telehealth or telemedicine. Please select whether you believe the following codes for telehealth services, with home as the originating site, should be reimbursed by Medicaid on a permanent basis beyond the PHE, in order to achieve optimal health outcomes in the most equitable way.



Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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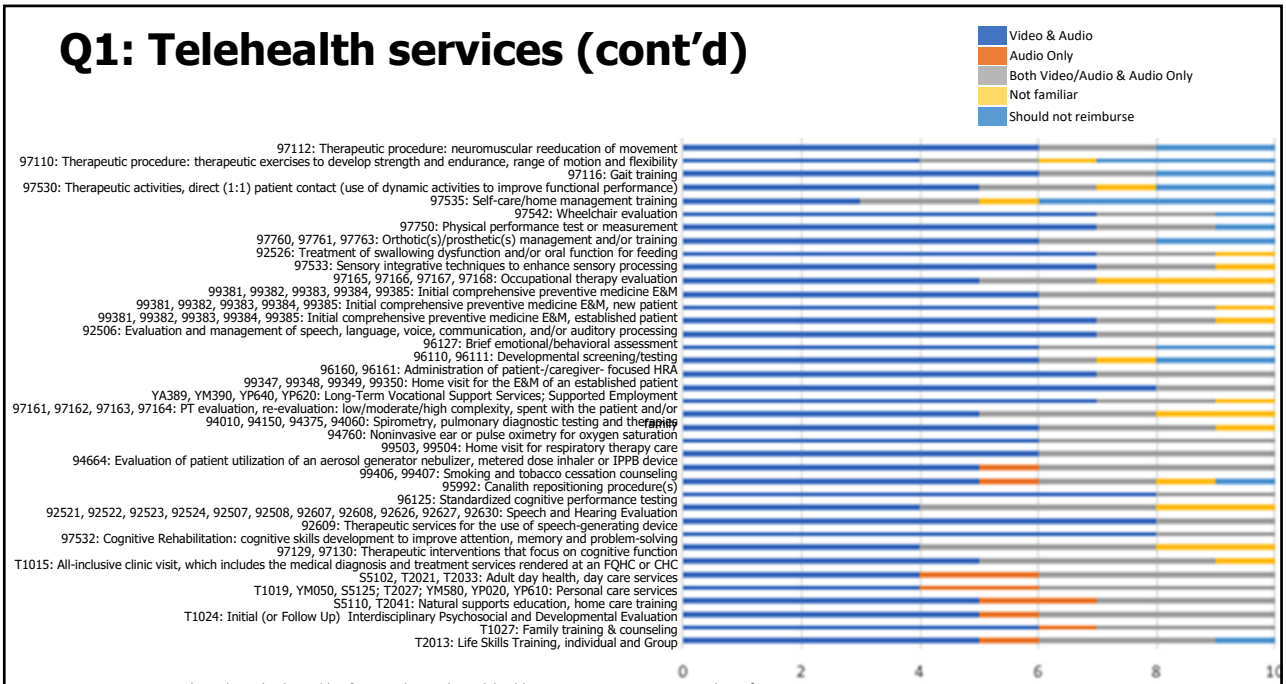
Q1: Telehealth services (cont'd)



Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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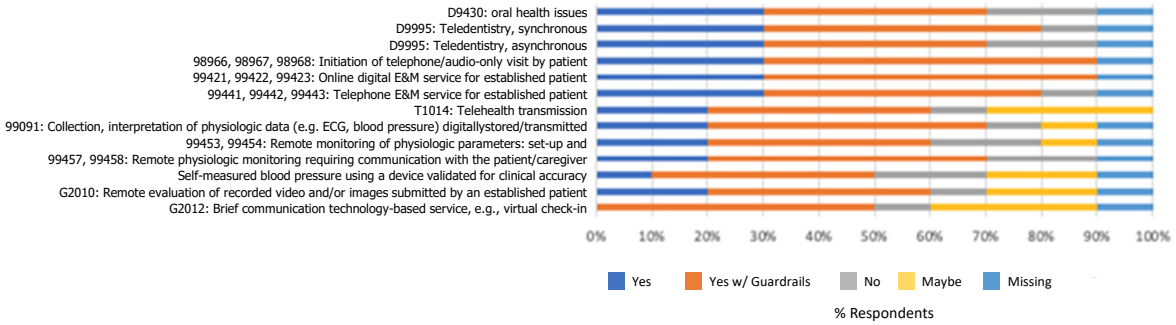
Q2: Telephone-based services

The following questions list a number of codes (CPT/HCPCS) for services that Medicaid beneficiaries generally receive by telephone. Please select whether you believe the following codes should be reimbursed as telehealth services, with home as the originating site, by Medicaid on a permanent basis beyond the PHE, in order to achieve optimal health outcomes in the most equitable way.



Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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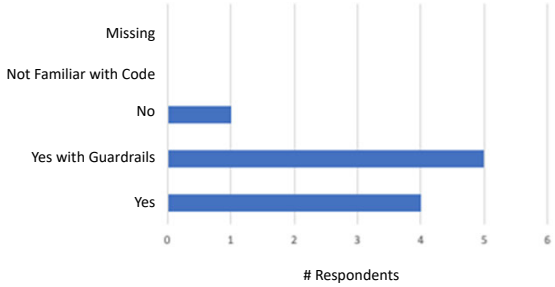
Q3: Interprofessional services

Prompt: The following question lists a small number of the interprofessional service codes for telehealth services. Please select whether you believe the following codes should be reimbursed by Medicaid on a permanent basis beyond the PHE, in order to achieve optimal health outcomes in the most equitable way.

99446, 99447, 99448, 99449, 99451: Interprofessional telephone/internet/electronic health records assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional



Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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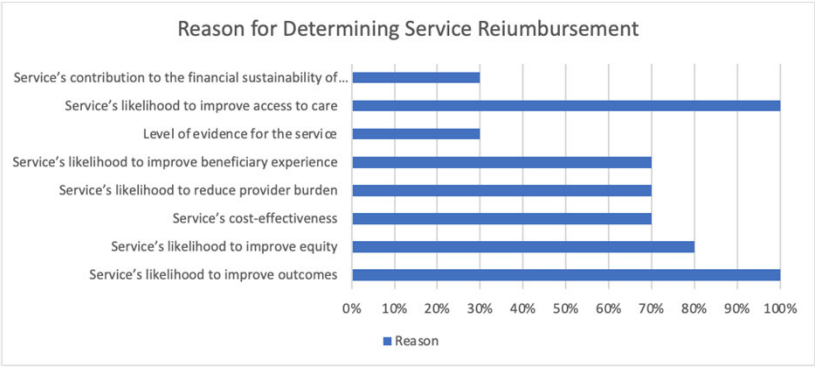
Q4: Reason for Determining Service Reimbursement

Prompt: Please select all the variables that contributed to you making the selections above



Source: Varatharajah S, Schnake-Mahl A, & Ostrovsky A. What Telehealth services are appropriate to reimburse for a Medicaid population to ensure equitable access to quality care? Being submitted for peer-review.

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Virtual pediatric mental health and speech therapy to overcome provider shortages

- Methods: Study of 105 Providers contacted across 24 states based on online directory of a well known regional carrier in May of 2021
- Key Findings:
  - Only 42% of ST, OT, and BH providers contacted treat children under 14 years old
  - Only 31% of providers that treat children are currently accepting new patients
- Only 10% of providers can provide ST, OT, and BH to children and their wait times are unacceptably high
  - 79.1 days for an OT appointment
  - 97.5 days for a ST appointment
  - 31.5 days for a BH appointment
- 14.29% of providers were outside of the 100-mile search radius
- 12.38% of providers had a disconnected or incorrect phone number listed
- Conclusions: Barriers exist to accessing pediatric ST, OT, BH therapy providers including 1) unavailable or non-existent providers, 2) excessive wait times, and 3) unreasonable driving distances.

Source: Kreuger B, Robinson R, & Ostrovsky A. Pediatric Access to Speech Therapy, Occupational Therapy, and Behavioral Health Services from a Regional Health Plan. Being submitted for peer-review.

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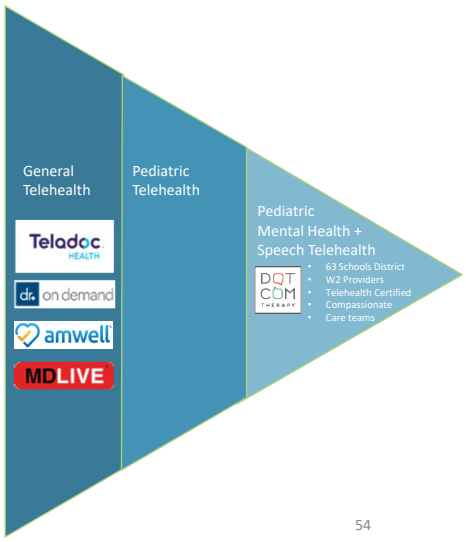
Considerations for insourcing vs outsourcing telehealth for brick/mortar providers

- Pitfalls to avoid
  - Providers must have adequate specialty experience (ie pediatrics)
  - There is risk of poor connectivity and technology challenges
  - There is insufficient provider training in virtual therapy best practices
- Attributes of high quality telehealth
  - Easy to use, secure platform
  - Exceptional internet connectivity
  - Services must be provided by certified, high quality providers



Source: Barry C & Ostrovsky A. Telehealth for Improved Pediatric Mental Health and Speech Development. NJAAP. 2020.

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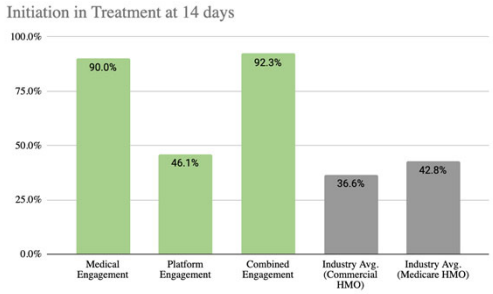
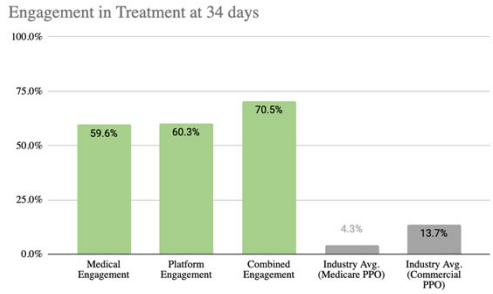
Initiation and engagement in treatment for virtual AUD treatment provider appear better than national average for in-person providers (Monument)





Source: Ostrovsky A, Krushel J, & Klein A. Initiation and Engagement with a Virtual Alcohol Use Disorder Treatment Provider. Being submitted for peer-review.

Objectives

Objective 1: Describe market failures and opportunities for innovation serving Medicare and Medicaid dual-eligible individuals

Objective 2: Identify new approaches to benefit coverage determination for emerging technology

Objective 3: Review trends and future directions in telehealth coverage and discuss supporting evidence

Objective 4: Recognize the foundational elements that are necessary to shift to value-based payments

Value based payment is accelerating in Medicaid

- Financial sustainability pressure from states given rising enrollment
- Pressure on providers accepting Medicare and commercial insurance to move into VBP arrangements
- Technology and service innovation enabling VBP in Medicare and commercial
- Business and technical drivers converging in the Medicaid space to finally make VBP come into the main stream

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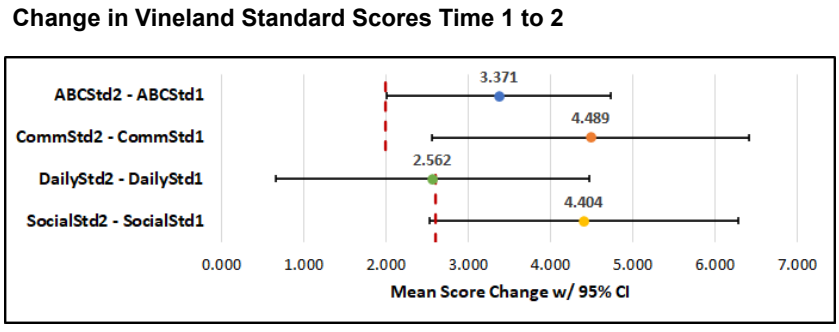
Data-driven, client-centric ABA treatment optimization improves functional outcomes



Kyo's data-driven, child-centric approach shows statistically and clinically relevant improvement in Vineland scores[1] (n=178)

Source: Ostrovsky A, Willa M, Cho T, Strandberg M, Howard S, & Davitian C. Data-driven client-centric ABA treatment dose optimization improves functional outcomes. In peer review.

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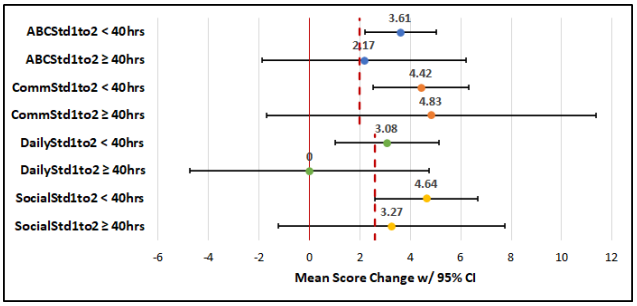
Data-driven, client-centric ABA treatment optimization improves functional outcomes

Standard Scores Relative to Hours of Service per Month

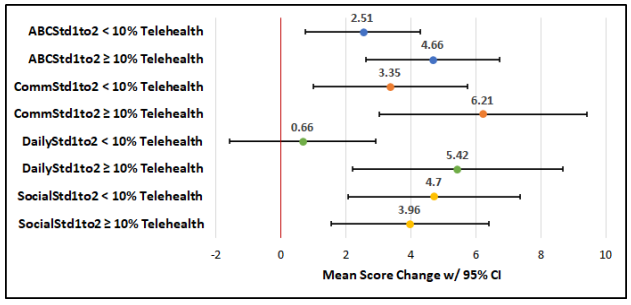


No statistically significant differences in the improvements in ABCStd, CommStd, DailyStd, and SocialStd scores when receiving ≥ 40 vs < 40 hours of ABA services per month

Source: Ostrovsky A, Willa M, Cho T, Strandberg M, Howard S, & Davitian C. Data-driven client-centric ABA treatment dose optimization improves functional outcomes. In peer review.

Data-driven, client-centric ABA treatment optimization improves functional outcomes

Change in ABCStd Score Change Relative to Percent of BEH Services Delivered via Telehealth

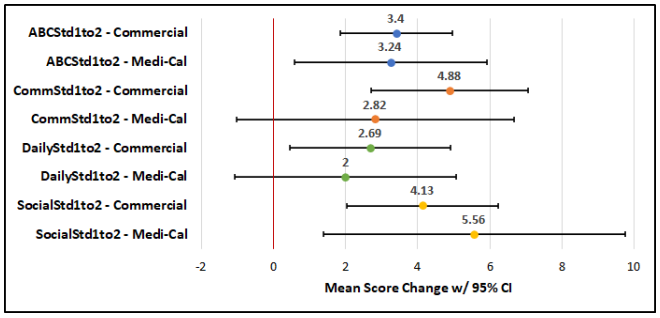


No statistically significant differences in the improvements in ABCStd, CommStd, SocialStd, and DailyStd scores with <10% BEH vs ≥10% BEH delivered via telehealth

Source: Ostrovsky A, Willa M, Cho T, Strandberg M, Howard S, & Davitian C. Data-driven client-centric ABA treatment dose optimization improves functional outcomes. In peer review.

Data-driven, client-centric ABA treatment optimization improves functional outcomes

Change in ABCStd Score Change Relative to Insurance Type



No statistically significant differences in the improvements in ABCStd, CommStd, SocialStd, and DailyStd scores with commercial insurance vs Medi-Cal

Source: Ostrovsky A, Willa M, Cho T, Strandberg M, Howard S, & Davitian C. Data-driven client-centric ABA treatment dose optimization improves functional outcomes. In peer review.

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Considerations for value base payment

- Agreed upon payment model between provider and payer aligned with provider capabilities and provider/payer goals
  - Generally start with Cat III APM
- Clear, simple, transparent, and frequently iterative quality measures
- Agreed-upon thresholds for payment tied to quality measures
- Simple invoicing and payment processes (Change Healthcare good for this)

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Considerations for value base payment

- Operational capability of providers to take on risk including
  - actuarial capabilities
  - data analytics
  - technology infrastructure to support value base payment
- Agile cadence (monthly to quarterly) of provider and payer meetings to ensure progress is being made toward shared goals
- Providers should be guaranteed steerage/volume in exchange for payers guaranteed savings

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Let's test your knowledge ☺

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Question 1: How did life expectancy for non-Hispanic black males change in 2020?

A. It increased by one year
B. It remained unchanged
C. It decreased by one year
D. It decreased by three years

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Question 2: What is the most common reason State Medicaid Medical Directors reference for deciding to reimburse Telehealth after the public health emergency caused by the COVID19 pandemic?

A. The likelihood of telehealth to improve outcomes
B. The level of evidence supporting the value of telehealth
C. The contribution of telehealth to the financial sustainability of the Medicaid program
D. The likelihood of telehealth to improve equity

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Question 3: One characteristic of optimal technology benefit coverage determination processes includes ensuring that the committee making coverage determinations has a diverse makeup of members

A. True
B. False

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Question 4: Digital therapeutics can be characterized as which of the following types of benefit categories? (select all that apply)

A. Pharmacy Benefit
B. Pharmacy Benefit as "other related item" for a drug
C. Device, DME, or Testing
D. Other mandatory or optional Medicaid benefit
E. All of the above

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Question 5: Along with clear quality measurement guidelines and quality measurement thresholds agreed upon with the payer, which of the following are also prerequisites for enabling community providers to engage in value base payment arrangements?

A. Ownership by a private equity company
B. The operational capability of providers to take on risk
C. Both A and B
D. Neither A nor B

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Thank you!

@andreyostrovsky

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