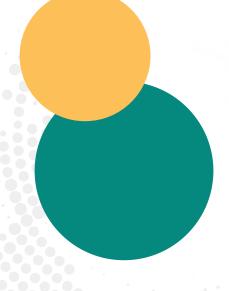
Streamlining Prior Authorization: Final Report & Recommendations

A NEHI White Paper





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About NEHI

NEHI is a national nonprofit, nonpartisan organization composed of stakeholders from across all key sectors of health and health care. Its mission is to advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent.

NEHI brings together expert stakeholder perspectives with relevant research to devise policies that speed the adoption of innovations.

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Executive Summary

The utilization management practice known as prior authorization (PA) has generated heightened controversy in recent years as payers and providers debate its benefits and burdens. Private and public health plans (payers) note that it is an essential part of their responsibility to ensure patient safety, decrease utilization of low-value care, avoid over-utilization of health care services, and direct care to appropriate, cost-effective health care settings. Providers reference administrative complexity and cost incurred in an effort to comply with a web of different PA requirements, lack of transparency in their development, and delays in patient care in their call to limit the services subject to PA. In this project, NEHI (the Network for Excellence in Health Innovation) assembled a group of Massachusetts payers and providers, together with employer and patient representatives (the "Steering Committee"), to determine whether they could agree on a set of reforms that might feasibly be implemented to reduce tensions around PA, considering a prioritized set of concerns. The Health Policy Commission (HPC) and the Mass Collaborative provided funding for this work to continue their efforts to improve PA's efficiency and effectiveness.

Over the course of three 2-hour meetings, the Steering Committee reviewed a scan of the literature on PA issues, implemented reforms, and proposed reforms. The Steering Committee also reviewed key findings from NEHI's interviews with national payers and various providers, discussed Steering Committee members' experiences and concerns, and finally, developed consensus around several action steps. In addition, the Steering Committee identified several areas of potential consensus for action, with the caveat that further discussion was required. In between Steering Committee meetings, NEHI solicited commentary on meeting summaries and proposals. NEHI worked closely with an Executive Committee, populated by members of the Mass Collaborative, in setting Steering Committee agendas and discussing various aspects of the project. NEHI also received comments on its final draft from the Steering Committee, many of which are incorporated in this publication.

The project could not focus on all the issues stakeholders raised, nor on all aspects of PA processes. Steering Committee members agreed to a focus on four areas in assessing possible reforms: the frequency with which PA is applied; the variation among payers in services/pharmaceuticals subject to PA; the variation in PA criteria; and the variation in documentation required by payers to satisfy PA criteria. After scanning the reforms identified in NEHI's research, the Steering Committee considered how well solutions addressed these priority issues. We explain both the reforms and the Steering Committee's commentary on pages 29-34. NEHI's recommended actions were formed from these exchanges.

Recommendations:

- We urge the HPC to work with payers and providers, likely leveraging the structure of the Mass Collaborative, to pursue three changes in PA:
 - A reduction in the number of PAs associated with treatments for extended courses of treatment, especially those associated with chronic conditions.
 - Expanded use of family codes. A reduction in administrative denials may be achieved by grouping like codes together in approving PA requests. Work to develop additional groupings will continue a number of reviews payers have already begun.
 - Alignment of medical necessity criteria for services for which third-party standards (e.g., InterQual or Milliman) are not available, focusing on areas in which denials are frequently associated with insufficient or incorrect documentation.
- HPC and the Mass Collaborative should support the creation of a Task Force by Executive Order to develop a roadmap that details policies and practices needed to enable diverse payers and providers in Massachusetts to adopt automated PA processes. Not only was there consensus that end-to-end automation of PA will reduce both burden and cost, but there was also strong agreement that automation must be planned and resourced. A multi-stakeholder Task Force can best produce a realistic study of operational requirements for automation, and work through fundamental issues regarding data sharing and uniformity. The Task Force would be equipped to assess the varied capacity of payers and providers, propose possible actions to address gaps in readiness, and make concrete, time-bound recommendations for needed resources and mandates.
- Information about services subject to PA by payers conducting business in the Commonwealth should be publicly available in a more accessible format, whether published privately or through a government agency. A consolidated format (with all payers' PA requirements) would provide payers, patients, and providers a picture of outliers and point to priority areas on which a focus might serve to reduce unnecessary variation. Publication of additional data might follow if this effort proves valuable.
- Interested payers and providers in Massachusetts should solicit support for a pilot program to use peer performance comparisons (social norms) as a substitute for PA to target inappropriate utilization practices. Several companies have focused on identifying normative utilization patterns for certain services. By providing individual physicians with their own practice data against these norms, and in comparison with their peers, companies have demonstrated in several studies that physicians reduced their utilization toward target benchmarks. The pilot would test whether this methodology can substitute for PA or provide a supplement to PA that is more transparent and useful for practitioners.
- Payers and providers should continue to pursue tests of change in individual contract
 negotiations and the outcomes of their work should be reviewed on a regular basis
 by the Mass Collaborative or the HPC. Gold-carding and waivers of PA associated with
 providers' assumption of performance risk (financial and quality) are two reform
 options that bear further review and development.
- IF material progress—recognized as progress against at least some of these recommendations—cannot be made in the next two years, NEHI would encourage the

Legislature to consider structuring mandatory collaboration among providers and payers to improve utilization management practices. Vermont's formally established Clinical Utilization Review Board (CURB) provides an interesting example, even considering Vermont's unique health care system.

The extended discussions conducted among stakeholders over an 8-month period provided deliberate and feasible options for pursuing PA reforms. Setting concrete goals and achieving at least some of these is essential. Ongoing engagement and discussion are important to evaluate changes and to continue to identify ways to reduce tensions around PA. Both the HPC and the Mass Collaborative can play important roles.

List of Abbreviations

Prior authorization (PA)

Massachusetts Health Data Consortium (MHDC)

New England Healthcare Exchange Network (NEHEN)

Health Policy Commission (HPC)

Division of Insurance (DOI)

Massachusetts Association of Health Plans (MAHP)

Massachusetts Medical Society (MMS)

Massachusetts Health and Hospital Association (MHA)

Blue Cross Blue Shield (BCBS)

Institute for Clinical and Economic Review (ICER)

Utilization Management (UM)

Angiotensin Receptor Blocker (ARB)

Angiotensin-converting enzyme inhibitors (ACE-Is)

Electronic prior authorization (ePA)

America's Health Insurance Plans (AHIP)

Center for Medicare and Medicaid Innovation (CMMI)

Center for Medicare and Medicaid Services (CMS)

Durable Medical Equipment (DME)

Clinical Decision Support Mechanism (CDSM)

Fee-for-service (FFS)

Power mobility devices (PMD)

American Medical Association (AMA)

Association of Black Cardiologists (ABC)

Pre-exposure prophylaxis (PrEP)

Qualified Health Plans (QHPs)

Council for Affordable Quality Healthcare (CAQH)

American Hospital Association (AHA)

American Pharmacists Association (APhA)

Medical Group Management Association (MGMA)

Health and Human Services (HHS)

Children's Health Insurance Program (CHIP)

Application programming interface (API)

Fast healthcare interoperability resources (FHIR)

Electronic Health Record (EHR)

Employee Retirement Income Security Act (ERISA)

National Council for Prescription Drug Programs (NCPDP)

Accountable Care Organization (ACO)

Center of Excellence (COE)

Acute Respiratory Infection (ARI)

Department of Vermont Health Access (DVHA)

Clinical Utilization Review Board (CURB)

Drug Utilization Review Board (DURB)

Global Appropriateness Measures (GAM)

American Imagine Management (AIM)

Project Overview

The goal of this project was to identify possible prior authorization (PA) reforms based on a review of national initiatives and consensus driven proposals from a Steering Committee of major stakeholders in Massachusetts, including payer, physician, hospital, employer, and patient representatives. Since we were aware of a separate Massachusetts initiative to pilot an automated process for PA, led by the Massachusetts Health Data Consortium (MHDC) and its New England Healthcare Exchange Network (NEHEN), we focused on reforms that supplemented or complemented automation. Overall, we accomplished the project's objective and identified additional work needed.

This report is divided into four sections. We first discuss our methodology. We then provide a scan of the literature on PA benefits and concerns, along with activities and recommendations to address the latter. In our third section, we review the Steering Committee's work and discussions. Finally, we recommend next steps based on overall project findings.

We gratefully acknowledge project funding from the Mass Collaborative and the Health Policy Commission (HPC). The Mass Collaborative, a voluntary, open organization of more than 35 payers, providers, and trade associations, has prioritized various aspects of PA for over a decade in addressing its mission to simplify and improve health care administration by increasing transactional efficiency, eliminating waste, and promoting standardization across the industry.* The Mass Collaborative is governed by an Executive Steering Committee comprising leadership of the founding members: Massachusetts Association of Health Plans (MAHP), the Massachusetts Medical Society (MMS), the Massachusetts Health and Hospital Association (MHA), Blue Cross Blue Shield of Massachusetts (BCBSMA), and MHDC. The Mass Collaborative designated individuals to function as the Executive Committee for this project.† The HPC, an independent state agency, develops policy to reduce health care cost growth and improve the quality of patient care. It has focused on addressing administrative complexity in health, including PA, in its list of priorities. The HPC holds a public cost trends hearings annually, convening health care market participants to address challenges and discuss opportunities for improving care and reducing costs across the Commonwealth. Representatives from the HPC participated in select Steering Committee sessions.

^{*}For example, it continues to work closely with the Division of Insurance (DOI) to standardize PA forms as required by Massachusetts statute (Chapter 224 of the Acts of 2012).

[†]Executive Committee members include Karen Granoff, MBA, Sr. Director, Managed Care Policy at MHA; Shane Rawson, Director, Inter-Plan Programs at BCBSMA, Michael Katzman, JD, Director, Public Government and Regulatory Affairs at BCBSMA; Elizabeth Leahy, Esq., Chief of Staff and Vice President of Advocacy and Engagement at MAHP; and Yael Miller, MBA, Director, Department of Practice Solutions and Medical Economics at MMS.

Methodology

NEHI is a non-profit, non-partisan organization with members spanning diverse sectors of U.S. health care, including, among others, patient advocates, payers, providers, biopharma, pharmacy, and academia. NEHI is committed to developing pragmatic policy and practice recommendations that incorporate different industry perspectives to improve productivity, drive better outcomes, and address unmet needs through innovation. Its location in Boston led to the formulation of long-term relationships with stakeholders in Massachusetts, which in turn enabled NEHI to propose this project.

NEHI's projects generally clarify issues through research and interviews and subsequently develop recommended approaches and solutions for those issues by convening experts and invested stakeholders. This project included a literature scan, more than 15 interviews (see **Appendix A**), and a survey. We used these to clarify current PA issues and to understand the experience of others as they adopted or experimented with reforms.

A Steering Committee (see **Appendix B**), consisting of 20 representatives from stakeholder organizations in Massachusetts,* provided guidance on the research conducted throughout the project, ongoing feedback on the conclusions drawn from research, points of consensus and concern, and recommendations on next steps. The **Steering Committee 3** summary provides details related to the PA benefits, concerns, and reform recommendations discussed in the first two Steering Committee meetings. **Appendix C** contains agendas for each of three Steering Committee meetings. NEHI also met regularly with the project's Executive Committee to examine presentations and obtain project feedback and acknowledges the importance of their engagement in advancing the project's objectives.

As an adjunct to the project scope, NEHI organized two presentations for the Steering Committee to inform the generation of possible solutions. First, as part of its efforts to coordinate its work with the MHDC/NEHEN pilot and to provide a greater understanding of automation solutions available, NEHI and MHDC/NEHEN sponsored a **webinar** that discussed several PA automation solutions. Second, in connection with work identified in its interview process, NEHI hosted two meetings with Martin A. Makary, MD, MPH, Chief of Johns Hopkins Islet Transplant Center and author of "The Price We Pay." Dr. Makary developed a provider-based process to reduce over-utilization of select services, which we describe later in this report.

This report does not attribute statements or views to individuals or organizations unless express permission was received from those entities. To encourage open dialogue, project participants agreed they would not utilize statements made during the project in their interactions with the state legislature or in connection with other efforts to advance individual positions.

^{*}To attend to patient and employer concerns, we included a representative from Health Care for All and from the Associated Industries of Massachusetts, but we acknowledge that subsequent work requires broader outreach.

Finally, the project recommendations focused principally on PA of clinical services and touched only briefly on the complex processes for authorizing prescription drugs. We highly recommend reading a publication by the Institute for Clinical and Economic Review (ICER).*

^{*&}quot;Cornerstones of 'Fair' Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals," (September 28, 2020).

Literature Review

Private and public health plans (interchangeably referred to as *payers*), including Medicare and state Medicaid programs, implement various strategies to ensure patient safety, decrease utilization of low value care, reduce costs, protect against over-use of health care services, and ensure care is delivered in the most appropriate setting. This practice is often referred to as utilization management (UM). The most common form of UM is PA, which requires providers to obtain approval from a health plan before delivering a certain service to patients. This process also ensures that the provider will be reimbursed for the services provided. Prior authorization requirements have grown over the past several years in an attempt to control high costs within the health care system and standardize care to ensure delivery of quality care across providers. Payers may differ in the application and administration of PA, and, for this reason among others, the process has garnered criticism for its administrative cost and burden, increasing calls for reform.

Methods

We performed a literature search through PubMed and OVID databases and the Internet, using search terms "prior authorization," "utilization management," and "step therapy." Sources in this review include peer-reviewed articles, trade publications (reports conducted by organizations or the government), and state and federal legislation. We excluded non-U.S.-based publications and studies conducted prior to 2000.

Angiotensin Receptor Blocker (ARB) Step-Therapy in Medicaid. States' Medicaid programs applied PA to direct providers to use angiotensin-converting enzyme inhibitors (ACE-Is) before prescribing ARBs. Both ACE-Is and ARBs are common drugs that demonstrate similar efficacy among individuals with hypertension. During the early 2000s, ARBs were still brand name only and there were several less expensive, generic options for ACE-Is. As Medicaid cannot exclude drugs from their formulary, some states placed PA requirements on ARBs that mandated an ACE-I trial before an ARB could be prescribed. Policies that implemented an ARB step therapy approach reported a 1.3% decrease in ARB users per calendar quarter, compared with policies that did not implement ARB step therapy requirements.

Prior Authorization Process & Purpose

Prior authorization, also referred to as pre-certification, prior approval, prior notification, prospective review, and prior review, is a process intended to determine whether an insurance entity will cover a prescribed product or service before it is provided to a patient.² Prior authorization is one example of a range of evidence-based medical management tools adopted by government programs like Medicare and Medicaid, as well as health plans, to ensure that patients receive optimal care based on well-established evidence of efficacy and safety. Payers will verify that the patient is insured, that the service requested is covered by the patient's plan,* and that the service requested is medically necessary.† Medically necessary care is generally defined as health care services that are needed to diagnose or

^{*}This internal control is applied to ensure patients receive in-network services and are not faced with unexpected and costly medical bills. The criterion for approval is therefore based on the patient's health plan product.

[†]The information used for medical necessity criteria often includes the patient's current medical conditions, medications, and medical history. "Medical necessity" is the broadest and most common use of PA and applies to medical services, some of which include surgeries and imaging studies, as well as pharmaceuticals.

treat an illness, injury, condition, disease, or its symptoms and that meet the standards of good medical practice in the local area.³ In addition, payers evaluate provider network restrictions and site of service.*

Prior authorization can also be used to coordinate care for patients who have undergone several classes of drugs or therapies to no effect, prior to approval for a higher-cost or more experimental treatment; this process is known as *step therapy*.† An example of step therapy is described in the insert.

Depending on the service to which it is applied, PA requirements vary based on the payer providing coverage for the service. The processes, however, generally follow the same protocol.⁶ (Reforms discussed within this report will address specific segments of the overall process.)

- 1. The provider assesses the patient and recommends a health care service.
- 2. Before ordering the service, the provider (the term provider may include clinicians, physicians, or non-clinical staff) must submit information on the patient to the payer.
- 3. The payer's clinical team, comprising physicians and other health professionals including specialists, reviews the PA request.
 - a. The service will be approved if the patient's circumstances match the criteria used for authorization.
 - b. The service will be denied if the patient's circumstances do not match the criteria used for authorization. At this point, the provider may go through a pre-determined appeal process.‡

Prior authorizations are generally submitted by providers or providers' staff via facsimile or telephone to the appropriate group within the payer's organization. Concerns related to process complexity and resulting delays in care, as well as administrative costs incurred by both providers and payers, led to the availability of electronic prior authorization (ePA) and PA automation, a "touchless" version of PA. Electronic PA and automation are discussed in detail under **Proposed Reforms.**

Prior Authorization Benefits

America's Health Insurance Plans' (AHIP) survey among payers§ cited the top priorities of their PA programs, which echoed literature findings. Ninety-eight percent of surveyed payers report that their PA programs aim to improve quality/promote evidence-based care, 91% report they protect patient safety, 84% report programs address areas prone to misuse, and 79% report they reduce unnecessary spending. Much of the peer-reviewed literature relies on data from public payers, which may reflect a proprietary approach to PA program data among commercial payers. There are, however, cost containment articles that use evidence from commercial payers. 8,9

^{*}For example, PA may be required before scheduling a surgery within a hospital rather than an alternative site of care, such as an ambulatory surgery center, as ambulatory surgery centers are generally less expensive sites of service.

[†]Step therapy can be used to ensure the patient has access to more cost-effective treatment (e.g., generic drugs vs. name- brand drugs).⁴

[‡]Clinicians on both the payer and provider side generally become involved in the determination of medical necessity but may also participate in decisions regarding site of care or alternative services if the patient encounters benefit limits. §AHIP surveyed 44 commercial health plans covering approximately 109 million individuals.

An example of PA's impact in ensuring that patients receive only medically necessary care is shown through the use of pre-approval in antibiotic prescribing;¹⁰⁻¹² PA has been shown to be an effective tool in Antibiotic Stewardship Programs.* MassHealth, Massachusetts' state Medicaid program, was successful in its effort to reduce the volume of high dose buprenorphine prescribing,¹³ an important therapy for substance-use disorders, using PA (see insert). In the Medicare program, PA has been shown to materially lower unnecessary use and spending. The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) found that PA for regular, non-emergency ambulance transportation for Medicare beneficiaries reduced unnecessary use by more than 70%, lowering total Medicare spending by 2.4%, all without impacting quality of care or beneficiaries' access to care.¹⁴

Prior authorization also functions to protect patient safety. A common example is the use of PA to flag potentially dangerous drug interactions. ¹⁵ Another example is related to the use of Durable Medical Equipment (DMEs). Medicare recently expanded their list of DMEs subject to PA to ensure patients are ordered equipment that works for their specific condition, ¹⁶ and not simply because the patient requests a specific model.†

Payers also apply PA when there is variation among providers in following evidence-based care guidelines. PA for oncology treatments is justified on this ground. A study by Grund et al.¹⁷ examined oncology treatment authorizations from seven payers across 43 states and found that the implementation of a web-based Clinical Decision Support Mechanism (CDSM) for services subject to PA resulted in a decrease in non-evidence-based treatments. Specifically, the percentage of non-standard treatments decreased from 30% to 11% over approximately one-and-a-half-years.¹⁷ Another study concluded that a private payer that implemented a CDSM within the PA submission process for chemotherapy drugs saved over \$5 million over the span of one year.¹⁸ The tool assessed patient drug interactions and provided real-time therapy alternatives. In this way, evidence-based treatments may also point to less expensive treatment alternatives.

Prior authorization clearly contains costs, overlapping with its other functions. Studies showing cost reduction include the elimination of unnecessary and high-cost care in favor of less expensive options. ^{19,20} In 2012, traditional fee-for-service (FFS) Medicare placed PA on the use of power mobility devices (PMDs)¹ in seven states with high rates of PMD fraud, (i.e., PMDs were prescribed to patients who did not meet medical necessity criteria). These states saw monthly expenditures drop from approximately \$12 million to \$3 million²¹ over nearly two years. After noted success of the PMD demonstration, Medicare expanded its use of PA to added services across states.²¹ Additional program expansion in both Medicaid and Medicare was recommended by the Government Accountability Office in 2018, citing benefits in reducing unnecessary care and associated costs.²³ We also identified a study in which a provider-led radiology management program partnered with a private Massachusetts payer to decrease utilization of CT and nuclear cardiology studies over a six-year period.⁹

^{*}Use of PA for antibiotics in an inpatient setting has been shown to decrease the number of antibiotic prescriptions and inpatient days by encouraging prescribers to order oral antibiotics or shorter antibiotic courses.

[†]Some interviewees argue PA is useful to prevent "imminent harm." They define two types of harm: 1) commission (e.g., a patient is ordered a wheelchair that is not designed to meet their needs, which could cause additional issues); and 2) omission (e.g., a patient continues to receive physical therapy without improvement).

The study implied that the elimination of unnecessary care and associated cost savings could be scaled across other health systems. Another study by Garcia et al.⁸ examined utilization data from the Massachusetts Medicaid program for long-acting opioid analgesics in 2002 and in 2005. The authors found that the program, which instituted PA to limit the number of doses prescribed and identify less expensive alternative treatment options, was successful in reducing long-acting opioid class use and claims among Medicaid beneficiaries, as well as decreasing opioid costs.⁸

Prior Authorization Concerns

There is significant qualitative (especially physician and hospital survey) data on the "burdens" of PA,* although quantitative data, especially relating to cost, also exists. Much of the literature highlights detrimental effects on patients engaged in continuous courses of pharmacotherapy. Drug regimens in mental and behavioral health services, when subject to PA, have been associated with disruptions in patient care. Palays in care were also found among rheumatology patients who were prescribed infusible medications. Patients were more likely to experience a delay in treatment (median 31 days, interquartile range 15-60 days) when the medication was subject to PA compared with patients prescribed the same medications without PA (median 27 days, interquartile range 13-41 days). Furthermore, the study found that when initial PAs were denied, patients were more likely to experience exposure to prednisone-equivalent glucocorticoids whose long term use has been associated with adverse patient outcomes.

In addition, physicians have protested that variation in PA requirements among payers and lack of transparency in medical necessity criteria create administrative burden that also leads to delays in care.† Survey data from the 2020 American Medical Association (AMA) Prior Authorization Survey²⁴ showed that more than half (54%) of the providers reported that PA always or often delays access to necessary care. Additional responses indicated that some PA restrictions have led to treatment abandonment or even hospitalizations.‡ Additional qualitative data argues that the application of PA may exacerbate health disparities among underserved and minority populations with respect to specific medical specialties. The Association of Black Cardiologists (ABC) Prior Authorization Workgroup surveyed physicians (90 percent cardiologists) and highlighted the significant burden associated with working in small facilities, as the staff typically cannot devote time exclusively to PA.²⁸ Sixty-four percent of respondents reported that they can only spare up to two hours per week to complete PAs.²⁸ Providers reported a disproportionately negative impact on underserved populations who rely on care from such facilities, both in terms of delays in care and provider-patient relationships.^{28,29}

^{*}Thirty percent of physicians surveyed in the 2020 AMA Prior Authorization Physician Survey reported that PA has led to serious adverse patient effects. Physicians were asked, "In your experience, has the PA process ever affected care delivery and led to a serious adverse event (e.g., death, hospitalization, disability/permanent bodily damage, or other life-threatening event) for a patient in your care?". Physicians were asked, "In your experience, has the PA process ever affected care delivery and led to a serious adverse event (e.g., death, hospitalization, disability/permanent bodily damage, or other life-threatening event) for a patient in your care?".

[†]Providers may order a service or medication, unaware that the order itself is subject to PA, until the imaging technician, scheduler, or pharmacist attempts to fulfill the order. This initiates a time-consuming back-and-forth exchange between the ordering provider and the service provider. Often, the service provider can submit the PA at this point, but some plans require the ordering provider to submit the PA. This action is referred to as retrospective PA. According to AMA surveyed providers, 60% of PAs are retrospectively submitted.²⁴ ‡Twenty-three percent of providers surveyed reported that patients often or always abandon treatment associated with PA, and subsequently attributed treatment abandonment to patient harm and a decrease in quality of care, with 30% of physicians reporting that PA has led to a serious adverse event, and 21% of physicians reporting that the need for PA has led to a patient's hospitalization.²⁴

Another study by McManus et al.³⁰ theorized that assigning PA to pre-exposure prophylaxis (PrEP) may reflect regional biases and contribute to lower levels of PrEP uptake (administered to individuals at risk for HIV) in the South, compared with other regions of the country. The authors examined whether PA was required for PrEP under qualified health plans (QHPs) in the Affordable Health Insurance Marketplace. Results indicated southern QHPs were nearly 16 times more likely to attach PA requests to PrEP than other regions.³⁰ Other plan characteristics did not account for this regional variation,³⁰ and it is well recorded that the annual incidence of HIV cases is highest in the South. Conversely, uptake of PrEP is lowest in this region.^{31–34} Because there is also evidence that the South is home to higher rates of stigma related to the LGBTQ+ community, stigma related to HIV, and more laws criminalizing HIV than in other parts of the country,^{35–38} the authors suggest that the decision to apply PA in this instance may reflect stigma associated with treatment for conditions more prevalent among specific populations.³⁹

Prior authorization guidelines vary by state, patient plan products, and associated PA requirements (e.g., medical necessity criteria, submission criteria, and services subject to PA across health plans). 40,41 One study found that providers spent significantly less time submitting Medicaid PA requests compared with private insurance PA requests (prior authorization took roughly 20 minutes to complete [beta = 20.017, p<.001]; Medicaid requests took 14 minutes [beta = -6.085, p<.001]), suggesting a more complex process or more scrutiny among commercial payers. Providers assert that a contributing factor to this administrative burden is the lack of transparency in PA requirements. Even when medical necessity criteria are relatively clear, providers evidence mistrust in their validity. Recent survey data compiled by the AMA largely reflects provider uncertainty surrounding the determination process when designing medical necessity criteria.

Finally, there is documentation that PA contributes to additional administrative time and cost burden for providers, as well as other health care stakeholders. Forty percent of physicians surveyed by the AMA state that they have staff who work exclusively on PAs, spending an average of 16 hours per week completing PA requests.²⁴ The American Hospital Association⁴² produced a report in which they discuss administrative burden‡ and the results of their 2019 survey, providing anecdotal evidence of cost estimates by various hospital systems.§ The Council for Affordable Quality Healthcare (CAQH) Index reported an overall increase in PA costs for payers and providers, though nearly 90% of the spending is attributed to providers, bringing the total cost to conduct PA in 2020 to \$767 million.⁴⁴ The report notes that "although [PA] only accounts for two percent of the total spend for medical transactions, the

§The AHA reported that a single "17-hospital system spends \$11 million annually just complying with health plan [PA] requirements" and that "a large, national system spends \$15 million per month in administrative costs associated with managing health plan contracts, including two to three full-time staff that do nothing but monitor plan bulletins for changes to the rules."

^{*}It is important to note that some payers are required to publish some PA requirements (e.g., services subject to PA) on their respective website. This does not facilitate an easy comparison of PA requirements across plans.

[†]Perceptions surrounding evidence in the formulation of PA requirements vary across payers and providers. For example, AHIP's survey found that 98% of payers reported that the criteria used for PA is based on peer-reviewed, evidence-base studies; however, 32% of providers who responded to the AMA's survey reported that PA criteria is "rarely" or "never" based on evidence or guidelines from national medical specialty societies, and over 10% of surveyed providers reported that they do not know how PA criteria is determined. The Department of Health and Human Services Office of the Inspector General produced a report that high rates of Medicare Advantage health plan providers and beneficiaries were denied payments and/or services due to inappropriate denials during 2014-2016, though only one percent of these denials were appealed.

cost to complete a [PA] remains the single highest cost for the health care industry."⁴⁴ Two recent studies focused on costs associated with utilization management for pharmaceuticals. The first examined the net benefits of PA using a model to estimate annual costs of PA for drugs requiring PA.⁴⁵ The authors found estimated annual costs of PA* to range from approximately \$1.9 billion to \$13.2 billion.⁴⁵ The second study took an expansive (or, depending on one's outlook, comprehensive) view of annual drug UM costs.† The study defined these as direct and associated costs stemming from PA and financial systems (such as patient cost–sharing).⁴⁵ It found the amount exceeded \$93 billion, incurred by payers, providers, drug manufacturers, and patients.⁴⁵ Costs incurred by patients, according to the study, were almost \$36 billion, followed by physician costs (\$26.7 billion). The study included costs incurred by pharmaceutical manufacturers at approximately \$24 billion, which

counted the costs of programs that supported physicians and patients in navigating utilization management and the costs of meeting co-pay or co-insurance requirements or otherwise offering free medications through patient assistance programs.⁴⁶

Example: Texas State Legislature. The 2021 Texas State Legislature approved House Bill 3459 on June 19, 2021, which requires payers to "gold-card" physicians who meet or exceed a specified benchmark for PA approval rates. It also requires PA to be reviewed by a Texas-licensed physician of the same or similar specialty as the requesting physician.

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Payer costs were estimated at \$6 billion. The authors provide suggestions to mitigate these costs, focusing especially on the need to promote "exchange of value-based pricing for value-based access," which, they note, would not—and should not—eliminate UM, as it will still have an important role in minimizing the use of inappropriate and over-priced medications. They advocate for additional studies to support movement in this direction.

History of Reform & Current Landscape

The American Hospital Association (AHA), AHIP, AMA, American Pharmacists Association (APhA), BCBS Association, and Medical Group Management Association (MGMA) convened in 2018 to craft a consensus statement on the tenets of PA reform.⁴⁷ The group identified five major areas for improvement within PA programs and processes:

- 1. Selective Application of Prior Authorization
- 2. Prior Authorization Program Review and Volume Adjustment
- 3. Transparency and Communication regarding Prior Authorization
- 4. Continuity of Patient Care
- 5. Automation to Improve Transparency and Efficiency

Though the AMA has annually surveyed providers to assess progress on reforms since the publication of the consensus statement, it found that providers perceive little improvement on these reform fronts.²⁴ This has led to several legislative advocacy efforts from the AMA and other state medical societies to pursue the passage of bills that would regulate PA. We discuss below both approved and current legislative and administrative efforts. MAHP has cited opposition to several current proposals; however, we were unable to identify such organizations.

^{*}The authors' definition of "costs" includes all financial costs associated with PA (i.e., additional health care costs due to PA non-adher-ence, costs to providers, costs to employer-plans, and labor costs for Pharmacy Benefit Managers and insurers). †The study was funded by Novartis Pharmaceuticals Corporation.

Federal Legislative & Adminstrative Efforts

To date, federal legislation has touched on the standardization of PA submission forms,* though it has largely focused on increasing access to care and guidance toward ePA and automated PA, particularly for behavioral health services. On at least one occasion, Congress directly addressed the inequitable application of PA to behavioral health services. The Mental Health Parity and Addiction Equity Act⁴⁹ was enacted in 2008 to ensure mental and behavioral health care services under commercial health insurance plans were not subject to stricter coverage and utilization standards than general care for other conditions. A decade later, Congress passed H.R. 6, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act,⁵⁰ with a provision (Section 6062) that requires the Secretary of Health and Human Services (HHS) to establish a standard ePA format for PA requests submitted for drugs covered under Medicare Part D.

The AMA presently supports a bipartisan bill to regulate Medicare Advantage plans that was first introduced to the U.S. House of Representatives during the 2019-2020 legislative session titled, "Improving Seniors' Timely Access to Care Act," 51,52 which would:

- Require standard ePA
- Direct HHS to require that payers provide real time PA decisions or drop PA for services with high approval rates
- Require transparency from payers regarding reports of approval rates, denials, successful appeals, and turnaround times for PA requests
- Minimize disruptions in established treatment plans, such as repetitive PA for patients with chronic conditions or changes in treatment plans based on formulary negotiations

Facing significant opposition, this bill did not pass committee during the 2019-2020 session. The AMA is continuing to advocate for its passage during the 2021-2022 legislative session (H. R. 3173).

The Centers for Medicare & Medicaid Services has also been instrumental in dictating advances in automated PA solutions.† In 2020, CMS selected the ePA standard to be used for drugs that require PA under traditional Medicare Part D programs;⁵⁴ electronic PA standards provide infrastructure for the electronic transmission of PA information.⁵⁵ The adoption of these standards for traditional Medicare has led to further PA standardization requirement efforts for additional Medicare Advantage plans.

In 2020, then CMS Director Seema Verma introduced a new rule⁵⁶ that would require Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs) to create and implement application programming interfaces (APIs) that are Fast Healthcare Interoperability Resources (FHIR)-enabled and integrable within Electronic Health Record (EHR) systems.‡ The Biden administration reversed the rule in February 2021 due to

^{*}Some have cited that such a form would not be appropriate for all services (e.g., pharmaceuticals), as the form could not feasibly include all necessary and service-specific information.⁴⁸

TCMS has mandated the use of CDSMs for specific diagnostic imaging services, under their Appropriate Use Criteria Program.⁵³ One interviewee discussed implementation of electronic CDSM and how it may serve as a more useful tool than PA, as opposed to using it in conjunction with PA. Though providers can override CDSM, a prospective pilot may compare provider utilization using CDSM versus PA. Those who override CDSMs must submit a PA.

[‡]The rule would also mandate that payers review urgent PA requests within 72 hours, and non-urgent PA requests within seven days. Additional requirements addressed transparency and insight into denied PAs and metrics on procedures that require PA.

objections from payer groups, a short comment period, and concerns surrounding its quick approval,⁵⁶ but is continuing to examine the issue of standardization as of August 2021.⁵⁷

A broader FHIR-based interoperability rule was put into effect by CMS in July of 2021⁵⁸ to broaden access to standardized health care data.* This will help facilitate the creation of automated PA solutions by private companies through API connections. There is little question that interoperability and automation will be subject of CMS's continued attention.

State Legislative & Adminstrative Efforts

The AMA tracks PA regulation and legislation⁵⁹ along six main criteria adapted from the 2018 Consensus Statement reform areas listed above.† Across these domains, 40 states have placed restrictions on how payers can apply PAs.‡ For example, Texas recently voted to approve legislation related to gold-carding⁶¹ (see insert). Only 9 states (MA not among them) and Washington D.C. do not have current pieces of legislation on PA reform under these domains.⁵⁹ This does not mean that individual contracts have ignored the consensus principles. For example, payers frequently include contract provisions that bind them to specific PA response times.^{61,62}

States' administrative reforms are primarily restricted to Medicaid and certain rules that health insurance commissioners can introduce within specific state health plans. The Employee Retirement Income Security Act (ERISA) restricts states' ability to make administrative rules affecting PA in employer-sponsored health plans.

In the coming years, there will be an opportunity to assess the impact of relaxed PA requirements associated with the COVID-19 pandemic, although confounding factors exist. These relaxed/removed requirements appear to have been applied primarily to Medicaid and telehealth benefits at the national level. In Massachusetts, PA was waived for all COVID-19 testing and treatment, telehealth, discharge to home health, skilled nursing facilities, rehab, scheduled surgeries and behavioral or non-behavioral health admissions at acute care and mental health hospitals. The AMA reports that 69% of physicians surveyed felt PA requirements were never relaxed or only temporarily relaxed during COVID-19.²⁴ It is possible that, in the case of telehealth, this modality was not widely adopted prior to the pandemic, and alleviation of PA requirements for telehealth services did not ease perceived administrative burden for surveyed providers.^{24,63} It is also possible that providers continued to submit PA requests, even under relaxed restrictions, to ensure coverage and reimbursement for services rendered.

^{*}The rule requires certain payers to make patient data available to patients through Patient Access APIs and provider directory information through the Provider Directory API.

^{†1)} Standardization of forms across payers; 2) ePA; 3) Response times; 4) Bounds on PA denials and retrospective denials; 5) Disclosure, appeal, and transparency; 6) Qualifications of PA reviewer.

[‡]Interestingly, only 16 states have requirements related to PA transparency for selected services. Such states include: Arkansas, California, Colorado (pharmaceuticals only), Delaware, Illinois (upon request), Indiana, Iowa, Kentucky, Maryland, Minnesota (upon request), Missouri (upon request), Ohio, Texas, Virginia, Washington, and West Virginia.

Massachusetts-Specific Legislative & Administrative Efforts

Massachusetts has strict requirements for PA and other utilization review conducted by payers and/or their utilization review organizations. Chapter 1760, Section 12⁶⁴ requires PA to be "conducted under a written plan, under the supervision of a physician and staffed by appropriately trained and qualified personnel and shall include a documented process to: (i) review and evaluate its effectiveness; (ii) ensure the consistent application of utilization review criteria: and (iii) ensure the timeliness of utilization review determinations." The law requires utilization review criteria to be scientifically derived, evidence-based, and developed with contributing physicians. The law also requires the criteria be made "easily accessible and up-to-date on a carrier or utilization review organization's website and upon request to the general public." Payers are required to make an initial determination regarding a proposed admission, procedure, or service within two working days. In addition, Chapter 1760, Section 16⁶⁵ sets requirements for payers in developing medical necessity criteria, including a requirement that the criteria be: "(i) developed with input from practicing physicians and participating providers in the carrier's or utilization review organization's service area; (ii) developed under the standards adopted by national accreditation organizations; (iii) updated at least biennially or more often as new treatments, applications and technologies are adopted as generally accepted professional medical practice; and (iv) evidence-based, if practicable. Any medical necessity guidelines criteria must be applied consistently by a carrier or a utilization review organization and made easily accessible and up-to-date on a carrier or utilization review organization's website to insureds, prospective insureds, and health care providers.

Further PA reforms specific to Massachusetts have focused on standardizing PA forms across payers and improving decision response time. In 2012, Massachusetts legislation directed the DOI to create standardized forms for services requiring PA. The forms cannot exceed two pages of questions assessing medical necessity criteria and once approved by the DOI, must be used and accepted by all payers and providers.⁶⁶ The law also stipulates that if a provider submits a standardized form, payers have two business days to respond to the PA request; failure to respond results in automatic approval. As mentioned, the Mass Collaborative created a Prior Authorization Workgroup⁶⁷ to collaborate with the DOI* in drafting and implementing several standardized PA submission forms. Thus far, the Mass Collaborative reports that they have produced standard forms in connection with certain behavioral health services (Level of Care, Psych/ Neuropsych testing, rTMS), prescription drugs (General Rx, Synagis, and drugs for treatment of Hepatitis C), and imaging (CT/CTA/MRI/MRA, PET CT, cardiac imaging, and non-OB ultrasound).

Massachusetts has also organized efforts to address health inequities. A 2014 law aimed at increasing access to recovery among individuals with substance use disorders mandated examination of potential barriers, including PA.⁶⁸ Five commercial Massachusetts health plans agreed in February 2020 to relax restrictions⁶⁹ on certain behavioral health services,

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^{*}The standardization of forms will be prioritized in additional specialty areas, as well as in electronic form. The DOI and Mass Collaborative will need to address related concerns, including the length of the standardized electronic form (i.e., electronic forms may be longer than the mandated two pages due to branching logic and certain service areas. For example, providers who serve patients with Autism are prone to extensive PA paperwork that cannot be contained to two pages), and electronic versions may not be equitable, as smaller practices may not be able to implement EHRs into their existing clinical workflow due to associated costs and energy.

including limiting PA.* Efforts to reform PA continue, as the Massachusetts State Legislature is currently considering various proposals that restrict PA^{70,71} and a bill^{72,73} that would both increase transparency throughout the PA process and set standards to specific segments of the PA process.† This bill would work to ensure patients have access to timely care.

Finally, MassHealth has implemented its own set of PA reforms that are either encoded in legislation or administrative rulemaking. For example, regulation requires MassHealth to respond to PA requests within two to three weeks, depending on the service.⁶¹

Proposed Reforms

Our literature review most frequently identified automation as an urgent reform effort, capable of reducing the length of the process (e.g., submission, approval) as well as the costs, for both providers and payers. We discuss this first. Advancing automation also has the effect of making other reforms more feasible, including a set of reforms we characterize by their focus on provider performance, both at the system and individual levels. We discuss this broader class of reforms next. Last, we examine reform efforts that must be piloted before being scaled. Reforms under this category substitute other forms of UM for PA.

Relating to Automation: Incentivizing Provider Uptake of Electronic Prior Authorization and Advancing Automation. Many resources refer to ePA and automation interchangeably or use automation as a verb to describe electronic advancement of PA. We define ePA as an umbrella term referring to the electronic method through which providers and payers send requests and receive decisions, respectively. Hautomation is a subset of ePA, but refers specifically to PA processes that minimize or avoid human intervention. Automation solutions/tools are integrated directly within a provider's EHR and begin the PA process at the time a service is ordered. The tool or system extracts necessary medical information based on payers' medical necessity criteria, auto-populates the submission form, and sends the request to the payer. Upon receipt of this information in a standardized format, in most circumstances, the payer's system is able to render an immediate response without further personnel review. There are several automation tools currently on the market that offer solutions to some or all segments of the PA process.

^{*}Plans include Harvard Pilgrim Health Care and United Behavioral Health d/b/a Optum; Fallon Community Health Plan and Beacon Health Strategies; AllWays Health Partners; Blue Cross Blue Shield of Massachusetts; and Tufts Health Plan.

[†]The bill proposes to "reform health plan prior authorization processes by 1) Prohibiting plans from modifying or rescinding prior authorizations issued unless inaccurate information is provided and improving transparency about prior authorization policies in communications to providers and consumers; 2) Create a committee, chaired by the Division of Insurance, to develop recommendations related to: promoting consistency in prior authorization policies and processes across health plans, establishing common time frames for the length of prior authorizations, ensuring active prior authorizations are continued when people transition to a new health plan, prohibiting prior authorizations for certain services that would improve chronic disease management, eliminating prior authorization requirements for prescription drugs and services that have low variation in utilization across providers or low denial rates, and overseeing the transition to electronic standardized prior authorization forms; and 3) Report on the progress of adoption of statewide standard forms. Analysis will be led by the Health Policy Commission."

[‡]There are multiple efforts to standardize data exchange between provider and payer systems. The CAQH has recommended standards using 278 transactions.⁷⁵ The Da Vinci Project also aims to create value in care coordination with the use of HL7's FHIR standards, which are similar to a guidebook for creating interoperable software for healthcare data exchange.⁷⁶

[§]Minimal to no human interaction is required by providers or payers unless the request requires additional information from providers' staff. It is likely that the system will never truly be "touchless."

[¶]EviCore's automated PA solution, intelliPath, is currently in beta testing to auto-populate PA forms using a CDSM-based EHR connection. This solution is not Da Vinci-compliant and must be implemented individually with providers.

Automated PA has been reported to reduce provider time spent on PAs (i.e., an average of 12 minutes per PA compared with traditional PA methods).⁴⁴ Automation has also been shown to be more cost effective,* result in faster payer responses than traditional channels,⁷⁴ and fewer delays in care.⁴⁸ Adoption of the CMS' National Council for Prescription Drug Programs (NCPDP) SCRIPT-standard⁷⁷ provides a prime example of the benefits of automation.†

Despite its obvious benefits, barriers to automation remain. First, interoperability must be accounted for through standard implementation guidelines (e.g., Da Vinci standards). Hille use of standard implementation guidelines is not essential to implement automation solutions, standardizing the way in which provider and payer systems communicate is crucial to scaling automation.‡ Establishing consistent implementation guidelines early, such as those supported by CMS, will increase the speed and efficiency with which automated PA solutions are adopted without necessitating substantial modifications when, as seems likely, standards are mandated to minimize the variation that detracts from achieving optimal efficiency. Second, uptake of ePA is necessary to advance automation. Surveys conducted by CoverMyMeds show that although almost all EHRs have an ePA solution, 60% of PAs still occur through traditional methods, reflecting low provider uptake. Many providers cite considerable doubts about the safekeeping of insurance information and other confidential patient information within EHR systems.

Proactive Authorization.§ Proactive authorization, or pre-authorization, is a patient-specific process that preapproves patients for downstream services related to their primary diagnoses. Advances in automation enable a more seamless pathway for reform. For example, Cohere Health created a semi-automated solution (i.e., not completely "touchless," but containing some Al-capabilities enabling an automatic decision from the health plan). Beginning at the time of diagnosis, providers may request and receive authorization for a full course of care/treatment.

A noted barrier to implementing proactive authorization is achieving agreement between providers and payers on specific requirements and time frames pertaining to services. ⁷⁴ Cohere Health has addressed this barrier by adopting guidelines issued by the American Academy of Orthopedic Surgeons for treatment of patients with musculoskeletal disorders. Humana Inc. has agreed to adopt this digital care pathway, through which CDSMs guide providers as they gather and submit information for an entire episode of care and are provided with an automatic decision from the health plan. Benefits to proactive authorization

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^{*}The 2020 CAQH report on automation estimated that providers could spend approximately \$3 per automated PA, compared with just over \$10 per traditional PA.⁴⁴ Furthermore, the CAQH Index estimates an additional \$16.3 billion in savings once full end-to-end automation is achieved.

[†]In 2013, the NCPDP created a four-part electronic transaction standard, called the SCRIPT-standard, to allow for standard payer forms, drug-specific PA criteria, and real-time PA request determination. These standards are currently utilized by Medicare Part D plans. These standards are currently utilized by Medicare Part D plans. These standards are currently utilized by Medicare Part D plans. The AHA produced recommendations in 2020 surrounding the standardization of the PA process and requirements for both payers and providers, which could be achieved through automation. The AHA calls for improvements in data sharing by recommending standardized formats for provider submission forms and that payers both respond to requests in a timely manner and provide detailed reasoning behind denials. Furthermore, the AHA navigates transparency issues by recommending a standardized format for providers to determine whether services are subject to PA and recommends payers follow a regular appeal process. Proactive authorization can refer to multiple reform policies and is closely tied to the reform that expands the use of ePA portals. Proactive authorization includes both real-time pharmacy checks and service benefit checks at the time a service is ordered and can bundle authorizations based on a patient's diagnosis. While both are possible through traditional PA methods, they are significantly easier to implement through ePA portals.

include fewer delays in patients receiving care/medications,* real-time benefit checks,† and an increase in PA process transparency.‡

This form of proactive authorization works well with established and relatively fixed courses of treatment. The selection of orthopedic procedures was purposeful. Providers have expressed concern about obtaining needed flexibility in treatment course changes that may be required for other services currently subject to multiple PAs. The types of changes throughout a course of treatment that require review will determine the benefits of proactive authorization as expanding its use among services is considered.



Rewarding Good Performance: The following reforms reward system and provider performance.§

Value-Based Arrangements. Under value-based arrangements, payers reimburse providers based on positive service/treatment outcomes, rather than the number of services/treatments performed. Much of the literature has suggested that once providers have "skin in the game," or assume responsibility for downside financial risk and quality performance measures, they should also be able to assume responsibility for PA. Providers agree in principle, but have noted the technical challenges of developing systems to manage PA. Studies in the field of cardiology show progress in decreasing utilization and increasing quality of care under value-based arrangements. Associated in the other hand, Vermont Medicaid found that removing PA for providers participating in the Accountable Care Organization (ACO) there, resulted in utilization increases.

More than 85% of AHIP's survey⁷ respondents who use value-based arrangements,⁸⁷ have recently begun to waive or reduce PA under this model.^{74,83,88} Of these respondents, approximately 50% believe automation of PA would incent additional providers to participate in value-based arrangements and subsequently assume responsibility for PA. Currently, many provider organizations ask payers to retain administration of PA, due to either a lack of resources to implement their own UM methods or due to a lack of infrastructure to determine which services should be subject to PA.⁷⁴

Centers of Excellence. A select group of both payers and large employers have developed contracts through which they waive PA, generally for circumscribed complex services, when

^{*}CoverMyMeds examined health system data and found that proactive ePA led to patients receiving their medication nearly two weeks faster, compared with retrospective ePA.⁴⁸

[†]The use of real-time benefit checks could address delays in care due to PA, as providers would be able to submit PAs and confirm which services require PA in real time and could avoid the risk of retrospective PAs.

[‡]Downstream PA services that follow treatment protocols pre-determined by clinical society guidelines could address transparency issues, clinical appropriateness of PA, and ultimately decrease the volume of submitted PAs.

[§]Though we focus here on provider incentives, we must include the AHA's recommendations that assign penalties to health plans for inappropriate denials and implement frequent audit processes to monitor plans that do fall outside the "normal" threshold for PA denials. AHA recommends that plans "be required to pay 50% above the normal payment rate if a denial is overturned by internal review and 200% of normal payment if a denial is overturned by external review or arbitration."

[¶]Vermont Medicaid's Chief Medical Officer suggested that these increases may be related to the limited level of financial risk providers assumed, as well as to the nascent development of providers' system controls.

those services are provided at a designated "Center of Excellence."* Payers customize criteria and evidence used to determine which hospital systems or provider groups qualify as a Center of Excellence (COE) or "high value" provider within a geographic area. 90,91 Criteria may include the rate at which certain services are performed (e.g., evidence that a provider is more judicious in its application of certain procedures).† Criteria also vary depending on the specialty area (e.g., congenital heart disease, infertility). 91 Under this type of reform, PA is waived for patients seeking specific services at the COE.

Several corporations^{92,93} plan to contract or currently contract with Centers of Excellence, including Lowe's, McKesson, JetBlue, Boeing, and Walmart.‡ Walmart has cited company cost savings and improved quality of life among employees who take advantage of their unique health insurance plan.⁹³ Centers of Excellence serve to concentrate care in a limited number of locations. While some argue that this decreases competition, the counter has validity: services rendered at COEs produce high quality health outcomes§ for complex services provided at a greater volume.^{90,91} The impact on cost, however, is not clear. In addition, the impact on reducing PA is also unclear. We are unable to determine what percentage of PA processes are waived in conjunction with the existence of designated COEs.

Gold-Carding. Payers use gold-carding to reward individual providers within a health system by waiving PA or automatically approving PA requests for providers who, over a set period, have high rates of approval on PA requests. ⁷⁴ The benchmark to become "gold-carded" varies across payers, from a 3–7% denial rate. Once this status is achieved, providers are typically able to maintain their gold-card status if they continue to perform at a certain threshold (usually 90% approval), as determined by an audit process.

A study on physician burn-out in Massachusetts specifically identified gold-carding as a feasible reform through which physician burn-out may be significantly reduced. ⁹⁵ Still, provider benefits from this reform may be minimal if only a few payers implement gold-carding and have different benchmarks. Standardized benchmarks could both mitigate this risk and significantly reduce physician administrative load. Ideas for variations of "gold-carding" were also shared throughout the interview process. ¶

One major barrier to gold-card implementation is the audit process, which can be viewed as burdensome for payers and providers alike. Another concern relates to inequities in achieving gold-card status; larger health systems have an advantage over individual providers in

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^{*}A prominent example is Walmart's direct contract with Cleveland Clinic for cardiac surgery. It also contracts directly with John Hopkins Hospital for joint replacement surgery and with the Mayo Clinic for transplants and cancer care. Other employers use payers as third-party administrators to achieve the same goal. UnitedHealthcare, for example, waives PA for bariatric surgery, among other services, if the service is performed at a designated Center of Excellence.⁸⁹

[†]Centers of Excellence, and the criteria used to define them, are not uniformly defined. Criteria are often linked to the rate of PA denials, but denials may not be reflective of the quality of care delivered, and therefore may drive inequities in defining COEs. ‡Walmart has contracted with the Cleveland Clinic, Mayo Clinics, and other Centers of Excellence for specialty services, such as hip and knee replacements, cardiac services, and certain cancers. Walmart's employee health insurance plan covers travel costs to Centers of Excellence, in addition to services rendered throughout the course of treatment.⁹⁴

[§]Optum reports that its COE patients are more likely to receive: more accurate diagnoses, higher survival rates, coordinated, patient centered healthcare, appropriate therapy, fewer complications, shorter length of inpatient stays, and decreased out-of-pocket costs, compared with non-COE facilities.⁹¹

[¶]One interviewee believes annual auditing of gold-carded providers would ensure continued proper utilization of services. Another interviewee suggests levels of gold-carding (e.g., gold, silver, bronze) through which providers would be granted a level of gold-carding based on their risk-sharing agreement and historic denial rates.

obtaining gold-card status as they have more time and resources to obtain the PA rates necessary for gold-carding.⁷⁴

Nonetheless, it is still unclear whether gold-carding providers positively impacts care delivery. In a study by Linder et al., ⁹⁶ the authors observed inappropriate prescribing patterns for acute respiratory infection (ARI) antibiotics through behavioral interventions that guided providers as they ordered ARI antibiotics. Orders were not subject to payer approval. Once the interventions were removed, inappropriate prescribing patterns increased. ⁹⁶ Although the study was not specific to gold-carding, it is likely service/treatment utilization will increase once providers are gold-carded, as they are not subject to payer approval.

AHIP reported that granting gold-cards to certain providers for select services can make the PA process even more confusing. Additionally, there is evidence that the initial "good" performance displayed to achieve gold-card status typically ebbs once attained and there is no opportunity for alternate recommendations to be given to the member and no check on self-referral. Efforts should be made to monitor Texas as it implements its gold-card program across payers and providers.



Requiring Pilot Testing: The following reforms are frameworks payers and providers may collaboratively implement to review, modify, or replace existing PA requirements. These are new and unproven proposals worth exploring. Pilot testing would be necessary to ensure these reforms prove to be solutions rather than added layers of administrative complexity.

Incorporating Fair Use Standards into PA Decision-making. The Institute for Clinical and Economic Review recently released a white paper to introduce transparent and equitable standards into the PA process for pharmaceuticals. This fall, they plan to release their ratings of payers' adherence to said standards. Their comprehensive paper focused on the method by which formularies are constructed and UM is applied to drugs currently on the market, as well as novel therapeutics. Based on a review of principles and recommendations to design fair and appropriate drug coverage policies, ICER developed "Ethical Goals for Access" and "Fair Design Criteria," and proposed implementation criteria to achieve the goals they outlined. ICER focused on five areas of reform, four* of which have direct implications for PA application. ICER proposed that PA should only be used when necessary to ensure appropriate care and should minimize administrative burden that has the potential to delay care. ICER advocated, for example, that payers use FDA approval language to establish the broadest possible coverage while acknowledging that there are circumstances in which narrower coverage requirements may be necessary and appropriate.†

^{*1)} Timing of development of PA protocols after FDA approval; 2) Clinical eligibility criteria for drug coverage; 3) Step therapy and coverage requirements for medication switching; and 4) Restrictions on prescriber qualifications.

[†]It must be clarified that 1) in some cases the use of diagnostic guidelines to triage patients by clinical acuity is not appropriate to treat all patients eligible under FDA regulations if clinical infrastructure is not adequate; and 2) clinical trial population participation guidelines may be stricter than FDA approval requirements.

The issue here is the extent to which a) voluntary adherence to the standards articulated can be achieved; and b) uniformity of uptake among payers.* ICER's undertaking was an ambitious attempt to achieve "fairness," as well as to reduce the negative impact that PA may have on patients, especially those who suffer from complex or rare diseases. Further exploration and support for adoption by national payers, such as CMS, would seem warranted.

Clinical Utilization Review Board. In 2010, the Vermont Legislature required the Department of Vermont Health Access (DVHA)¹⁰⁰ to appoint a Clinical Utilization Review Board (CURB).† The CURB was tasked with making recommendations to DVHA regarding coverage, unit limitations, place of service, and appropriate medical necessity of services in the State's Medicaid program. The CURB was directed to consider "the possible administrative burdens or benefits of potential recommendations on providers, including examining the feasibility of exempting from prior authorization requirements those health care professionals whose prior authorization requests are routinely granted." Board members, including practitioners with diverse experiences, make recommendations to the DVHA Commissioner to implement alternative solutions to UM and/or waive PA.‡ Meetings and meeting minutes are public.

In discussions with the Chief Medical Officer and Director of Operations for DVHA, he observed that discussions were productive in identifying when utilization controls were appropriate, including the need to prevent harmful utilization from outlier providers. Each year, the CURB considers adding certain services to "imminent harm" codes, including errors of commission and omission. He noted that providers have accepted these determinations and BCBS has adopted recommendations put forth by the CURB.

To our knowledge, clinical utilization review boards have not been implemented in other states; however, Drug Utilization Review Boards (DURBs) are prevalent across the U.S., including in Vermont and Massachusetts, and may provide an additional framework with which formation and implementation of a clinical utilization review board may be considered in other states.

Global Appropriateness Measures. Global appropriateness measures (GAM) are a new, provider-driven solution to identify low-value care and reduce clinical waste. ¹⁰¹ Using stakeholder input§ and current medical literature, GAM has developed measure of appropriateness, or metric algorithms, in clinical areas that appear to have variation and overuse. Payers and providers can define utilization thresholds and apply these to their own datasets for specific services within specialties (e.g., currently, there are 12 measures related to Mohs surgery).

^{*}A possible reform should incorporate the adoption of principles encompassed in ICER's fair design and implementation criteria. For example, in Medicare Part D plans, it was found that there was significant heterogeneity in the time it took for plans to determine drug coverage during months post-FDA approval. This could cause patient harm by delaying access to novel therapeutics and/or high out-of-pocket costs. In direct response, ICER proposed that plans implement regulations to complete coverage policies within three months of FDA approval and that coverage during the immediate period following FDA approval should use FDA label language for all PA requirements.

[†]The CURB is comprised of 10 clinicians appointed by the Governor and is assigned with: reviewing and identifying appropriate medical utilization as it relates to medical necessity, cost-effectiveness, and feasibility. The CURB then presents their findings and recommendations to the Commissioner.

[‡]The Board examines clinical data for specific services subject to PA, specifically services readily approved, at low cost, or those that pose zero risk to patients.

[§]Over the past six years, Dr. Martin A. Makary and his team have conducted more than 1,000 interviews and focus groups with specialists across various fields of medicine to identify patterns of overuse in their area of expertise.

Health plans and providers may join the GAM consortium, through which they would receive access to a full library of measures. They may also select to target certain specialties, without utilizing the full set of measures.* GAM provides various levels of support, including data analysis, threshold definition, and guidance to reduce inappropriate utilization. For example, GAM may prepare "Dear Doctor" letters.† GAM asserts that clients have reduced variation in this way, and that the "Dear Doctor" letters have led to long-term behavior change. 102

Though GAM has not targeted services subject to PA, a possible reform effort could include creating and implementing measures of appropriateness for services subject to PA. Providers and payers could agree on select services subject to PA that have high rates of approval and/or services subject to wide variation in utilization. Payers could then apply GAM's methodology to avoid imposing PA for select services they are currently evaluating and avoid an additional layer of administrative burden. This effort could also be seen as an alternative to gold-carding and is discussed below in our Recommendations.

^{*}GAM's analyses also assist health plans in determining areas to target based on their networks' utilization patterns and potential economic benefits.

[†]Letters present unique service utilization data. The letters also identify the threshold within which providers should aim and show the recipient where they fall within the distribution.

Steering Committee Discussions

Steering Committee 1: Introduction.

Steering Committee members introduced themselves during the first meeting and shared their perspectives on the circumstances in which PA is effective, as well as their ideas for improvements in PA. Steering Committee members echoed many of the benefits and concerns of PA reflected by both payers and providers in the literature.

Providers noted difficulty in adapting to payers' varied applications of PA, as well as their different PA requirements. They voiced concerns about delays in patient care resulting from PA processes, especially with respect to repeated PA for chronic disease treatments.* They questioned the need to apply PA to services with low denial rates. They also noted that they experienced delays in reimbursement related to "technical" applications of PA.†

Providers ascribed benefits to PA as well. They found PA effective to ensure appropriate review of high cost, new and experimental treatments. In some cases, providers also noted that PA was an effective means for reducing low-value diagnostics and therapies that were outside evidence-based practices.

Agreeing with these benefits, payers characterized PA as a fundamental tool in meeting their responsibilities to employers and members. Health plans cover only "medically necessary" services to ensure safe, cost-effective care management with the overall goal of improving quality of care for members. Some payers also cited PA as a helpful means to alert patients and providers to the availability of alternative, more cost-effective (and less restrictive) treatment options. PA can also be used to protect members from exceeding benefit limits and avoid surprise billing based on network management controls.

The following remedies were most often mentioned by Steering Committee members as ways to improve PA:

- Automation
- Removal of PA for services rarely subject to payer denials
- Standardization of policies among payers
- Expanded use of code families or creation of additional code groupings (Appendix D)

Following this discussion, NEHI presented preliminary findings from its literature scan, which provided an overview of PA reforms adopted by payers in four categories: 1) waiving/modifying PA in value-based arrangements; 2) proactive PA; 3) gold-carding; and 4) automation. These are described in the Literature Review above as well as in **Appendix E**. NEHI received comments on the reforms as well as recommendations for interview subjects and additional

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^{*}As noted further below, we did not obtain data in connection with either provider or payer claims. We provide illustrations if these were offered. In connection with the concern about the impact of PA on those with chronic conditions, Health Care For All noted that this complaint was a frequent subject of calls to its consumer hotline. HCFA further expressed concern about the impact that PA may have in discouraging patients from pursuing treatment in a timely manner with additional process acting as a barrier to access. The providers said that claims were denied, for example, when they received authorization for the use of certain medical devices or therapeutic interventions and, in practice, used closely related interventions with different Current Procedural Terminology (CPT) codes. As clarified later, providers produced evidence of variation, but we did not obtain data documenting providers' other observations, though these are also reflected in the literature.

research. NEHI also asked Steering Committee members to provide written feedback on their "wish list" for reforms, criteria for evaluating any changes in PA, and thoughts on major impediments to achieving reforms.

Steering Committee 2: Further Exploration.

The goal of the second meeting was to review PA reforms discovered in our literature scan and interviews for the purpose of identifying points of consensus around feasible options. To evaluate the options, we took time to characterize the principal issues they were intended to address. There was consensus from the Committee that the issues could be classified in four categories based on prior discussions and additional findings from the literature.

The frequency with which PA is applied. NEHI noted that surveys conducted by AHIP⁷ and AMA²⁴ highlight discord on this topic.* Payers take various steps to limit the application of PA, including review of PA that is frequently approved. Providers nevertheless perceive PA to be over-used, even when applied to a limited percentage of overall services. Both payers and providers concurred that automation would relieve the burden of PA considerably, if uniformly implemented and standardized.

The variation among payers in services/pharmaceuticals subject to PA. A provider participant presented a chart of different PA requirements and examples of differing submission forms among health plans doing business in Massachusetts to illustrate the issue. See Appendix F. Providers note that variation is challenging for office staff and physicians alike. While, as stated, most plans regularly review the rate of denials for their PA processes, they come to different conclusions regarding the utility of PA and make different decisions about removing PA based on similar outcomes. Participating health plans noted that they view decisions about PA as important to marketplace differentiation.

The variation in PA criteria. Most insurance companies and providers use InterQual or Milliman standards to inform the medical necessity of care.† Providers, however, report that variation in medical necessity criteria continues to be a clinical obstacle and an administrative burden. It is unclear whether this perception is based on PA for services for which standards are unavailable. This affects patients who may be eligible for a service when covered by one plan but not by another. Moreover, for providers, the issue merges with mistrust about the criteria payers employ and how those criteria are applied.‡

Variation in documentation required by plan to satisfy PA criteria. Plans use different forms to vet the medical necessity of services, even where the criteria for approving a PA

AMA findings included: providers complete 40 PAs/week; Forty percent of providers have hired additional staff to exclusively work on PA; physician offices spend an average of 16 hours a week on completing PA.

†According to our interviews, Massachusetts payers use one of these two standards in constructing approximately 75% of PA criteria; national payers (e.g., Aetna, Cigna, United, Humana) likewise rely on these standards.

‡In addition, providers noted that payers' use of third-party vendors for a portion of PAs creates administrative complications.

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^{*}AHIP's key findings included: plans review their PA Lists at least annually (100% for prescription drugs; 95% for medical services); 83% of plans make fewer than 11% of prescription medications subject to PA; 10% subject between 11%-24% of medications to PA. Sixty four percent make fewer than 11% of medical services subject to PA, with another 28% subjecting between 11%-24% of medical services to PA; no responding plans subject primary care services to PA. The most frequently subjected services to PA are Specialty drugs (98%); High-tech imaging (89%); Genetic testing (86%); DME (75%) and high-cost brand-name drugs (70%).

request may align. We cited differences in forms used among American Imaging Management (AIM), Aetna, and MassHealth for authorizations requests. (See **Appendix F**).

Discussion of Solutions and Preliminary Preferences. NEHI described 11 solutions based on its research, interviews, and Steering Committee input. In two break-out sessions, participants voted—on a preliminary basis—to prioritize the solutions, in consideration of the issues above as follows.* The Committee's initial discussion of these solutions is summarized in **Appendix G**. Because Steering Committee 3 was devoted to exploring these solutions more fully, we review them in detail in the next section of this report.

- 1. Remove PA for certain services with high rates of approval
- 2. Remove multiple and repeat PAs for a continuous course of treatment
- 3. Create incentives for uptake of electronic PA
- 4. Remove PA for certain physicians based on their performance
- 5. Expand use of family/group codes.
- 6. Establish processes that require collaboration.
- 7. Remove PAs for physicians in ACOs or risk-based arrangements.
- 8. Embed care pathways/utilization management on a condition basis.
- 9. Substitute payer PA with use of clinical decision support tools.
- 10. Create economic incentives to reduce PA.
- 11. Establish processes that incent collaboration.

Steering Committee 3: Forming Consensus.

The goal of the final Steering Committee was to develop consensus on feasible and preferred options for reforming PA to address the issues discussed.

Most of the solutions presented were intended to reduce the frequency of PA and were discussed first.

Require the removal of PA for services with high rates of approval. We did not achieve consensus on this point. Payers oppose this solution and provider support was stronger in our initial discussions than at the conclusion of the project. There are two principal issues from payers' perspective: a) a regulatory mandate that removes discretion is overly blunt and may have unintended consequences; and (related) b) there is data indicating that PA has a sentinel effect in avoiding costs, especially with respect to low value, low risk services (as with many forms of physical therapy). A further comment seems warranted: it is not clear whether the removal of PA for services that are generally approved would have a significant impact in ameliorating providers' concerns. We have not been able to identify data indicating what percentage of PA processes these represent or to evaluate the burden associated with gaining approval for this subcategory of services. The lack of available quantitative data to size the issues is an overall weakness of our report.

Remove PAs for services that are part of a continuous course of treatment. There was substantial consensus on exerting efforts to avoid PA for an established, continuous course of treatment, especially for chronic conditions, (which would address one of the primary

^{*}We note that there was some confusion about overlap and scope in the solutions presented, which we clarified after the meeting. Accordingly, the ranking was directional, but not determinative in our final discussion.

concerns raised by Health Care For All based on patient hotline calls), but there was not consensus on the details of reform. Some members of the Steering Committee noted that PA was useful–even for chronic care treatments—to identify therapies and medications that were no longer effective or could be replaced by more effective treatments.

Our discussions encompassed ways to address these concerns, at least to reduce the number of PAs in extended courses of treatment, especially as electronic solutions become available to identify care pathways. As suggested in some of our interviews with providers, payers could extend the periodicity of review. Some stakeholders also suggested that payers could narrow the group of treatment courses that require periodic PA eliminating PA for evidence-based treatment protocols.* To address payers' goals of ensuring that providers continue to apply the most effective treatment options (after an initial PA), NEHI observed that payers could notify providers of new treatments in communications to relevant specialists and in authorizations for new patients with the condition(s) at issue. Physician participants cautioned, however, that it is not always possible to determine whether a drug therapy or treatment course is no longer effective and PA for this purpose may not be evidence-based. For these reasons, and because this change would affect patients more directly, further work on implementing this solution seems warranted and is reflected in our recommendations.

Create Incentives for the uptake of electronic PA and automation. Committee members agreed with this solution. Providers mentioned concerns about enabling payers to increase the number of services subject to PA, but these did not lead them to oppose the value of moving to electronic PA and automation, which have been shown to reduce costs and administrative burden.† The issue here is how to identify those incentives that will equitably allocate the costs of automation infrastructure and process change and ensure implementation of standards that eliminate process variations among payers. Our recommendations offer a process for advancing this issue that complements the efforts and work of MHDC/NEHEN in piloting automated PA.

It is worth mentioning here the Steering Committee's discussion of creating economic incentives to reduce the use of PA, essentially establishing a separate price for clinical services that are subject to PA, as suggested by Cutler, to reflect the costs of the process. Committee members acknowledged that the suggestion was rational. It may be more appropriate to consider it in the context of encouraging the use of electronic PA, which could be applied to all services. This is further discussed in our recommendations.

Reward physicians and/or health systems for adherence to evidence-based standards ("Gold-Carding"). Gold-carding generally references payers' decisions to waive PA requirements (grant a gold card) for a set of services because the physician or health system has achieved a high rate of approval on PA requests for that service(s). There was consensus on the logic of removing PA for those who demonstrate that they are practicing in accordance with recognized standards, although (as accompanying audit requirements demonstrate) a

†It seems likely that the market will act as a constraining force here.

^{*}Payers have raised concerns about whether removing PA in this manner would leave safety concerns unaddressed. In our interviews, providers noted that advances in the electronic medical record and medication reconciliation safety protocols weaken the need for PA in this context. In any event, NEHI notes that patient safety concerns do not apply uniformly for all evidence-based protocols and that this remains an opportunity for more selectively applying PA.

lack of confidence that "good" performance is sustained once PA is waived. There was also one objection to the method by which payers determine gold card entitlement. The rate of approval may not only reflect a physician's adherence to evidence-based standards but the extent to which the physician's office can produce required documentation. The concern is that practices with low commercial payer mix are at a disadvantage because they are unable to afford necessary staff or sophisticated revenue management assistance and may be passed over for gold-carding opportunities.

The more significant issue, at least for office staff, if not for physicians themselves, is that the allocation of gold cards to some, but not all physicians in a practice introduces another form of variability. Some physicians will have PA waivers from some plans, which requires the determination of the patient's insurance coverage and status of the patient's ordering physician. This variability can be reduced somewhat by "gold-carding" on a system or practice basis.*

Another potential burden or additional cost relates to the audit processes associated with gold-carding programs. Payers require utilization audits to determine changes in practice as a condition of extending gold card PA waivers and have pointed out that once reviews are removed, utilization increases.† Proponents of automation note that it will substantially reduce audit costs.

All told, while waiving PA for some physicians or systems had support, it was not strongly endorsed considering the issues noted above, as well as the disfavored name used to describe the waiver process,‡ explains the greater push by physicians to remove PA for all services with high rates of approval. We do, however, include gold-carding in our recommendations, in addition to a pilot alternative to gold-carding that is built on the principal that physicians who adhere to evidence-based practices need not be subject to PA. (See Recommendation D).

A related note is worthwhile. There was considerable payer support for waiving PA in connection with providers who are designated as Centers of Excellence. Self-insured employers (and payers) recognize providers as Centers of Excellence with respect to complex procedures and treatments based on demonstrated quality and cost outcomes. While Centers of Excellence function to consolidate complex care and narrow patient choice, the concept serves to incentivize providers to demonstrate value. The designation, unlike gold-carding, is not dependent on PA approvals, but instead relies on care outcomes and negotiated standards between payer and provider.

Remove PA for physicians (and systems) that assume "substantial" financial risk in payer contracts. This recommendation received considerable support, although both payers and providers are averse to any mandates in this area, preferring that the issue to be negotiated in individual contracts between payers and providers. Payers want discretion to

^{*}BCBS of MN took this position, reasoning that the system should be responsible for improving its physicians' performance. According to BCBSMN, providers were unwilling to enter this arrangement.

Tee "Effects of Behavioral Interventions on Inappropriate Antibiotic Prescribing in Primary Care 12 Months After Stopping Interventions" by Linder et al. (2017).

[‡]Physicians object to the inference that only those physicians who are "gold-carded" are high quality.

determine what constitutes substantial risk, as well as the extent to which they delegate PA responsibilities. Indeed, providers and payers shared the view that they should be able to determine whether to delegate PA responsibilities to the provider, noting that providers were not uniformly equipped to adopt the process effectively and efficiently. Integrated hospital/physician systems more strongly endorsed the assumption of PA in connection with contracts in which they assumed downside financial risk because they had incentive to monitor utilization and attendant control over physician behaviors. They also tended to have more sophisticated systems in place to monitor physician ordering and utilization. Conversely, physicians and payers expressed concern with misaligned incentives between hospitals and physicians; the provider with risk may, for example, have little influence on the use of third-party testing and imaging.*

The following solution is focused on reducing variation in services and pharmaceuticals subject to PA, noting that several solutions above would also address this issue.

Establish processes that require or incentivize collaboration. We focused on two ideas. The first built on Vermont's Clinical Utilization Review Board. Our interview with Scott Strenio, Chief Medical Officer for Vermont Medicaid, indicated that the Board was productive in identifying services for which PA was useful (services classified as having the potential to cause "imminent harm") and services for which PA should be waived. Dr. Strenio noted that the CURB's recommendations also reduced variation in payer policies because BCBS, the major commercial insurer in Vermont, often followed the CURB's lead.

The Steering Committee generally endorsed the idea of a voluntary council, with notations that a council including commercial payers would need to address anti-trust issues. Some Steering Committee participants noted that the Council could address a variety of issues, including variation in medical necessity criteria. Payers were not supportive of discussion scope that might affect their discretion either in designing and implementing PA protocols/programs. We comment further on this solution in our recommendations.

The second method to incentivize collaboration and, more importantly, inspire reform, is through the publication of data that publicizes the issues and increases accessibility to all stakeholders. We discussed requiring an annual classification of PA requirements by all payers doing business in the Commonwealth. This would reveal variation among payers in a way that PA descriptions on individual websites does not and might provide an early signal to providers about potential new PA requirements (e.g., where one or two payers initiate new PA processes). Providers on the Steering Committee supported this idea; payers on the Steering Committee agreed that consolidating information in one place would be useful but expressed concerns about implementation challenges. Legitimate issues relating to formatting the information and maintaining its currency require consideration. Creating a website with links to individual payer websites might resolve some of these issues, provided the landing page allows payers, providers, and health plan members to compare PA requirements. It is worth noting that a handful of states now require plans to provide information on PA denials, with varying levels of specificity relating to rate of denials, the specialty at issue, and reason for

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^{*}It seems worth noting that there is evidence that can be examined further on the impact that providers' assumption of risk has utilization trends. We found little data in the literature, although it seems likely that Medicare has studies but our interview with Vermont's Medicaid CMO is worth further discussion.

denial.⁵⁹ More ambitious information sharing will likely garner greater concern from payers but may be necessary to prompt change. We discuss this solution in our recommendations.

The following solutions are focused on reducing variation in PA medical necessity criteria.

Embed care pathways/utilization management on a condition basis. Prompted by the desire to automate more of the PA process, reduce multiple PAs for different services associated with a given condition, and improve provider confidence in the clinical criteria used in PA determinations, several vendors are working with physicians to create automated care pathways. Throughout this project, we heard from **three vendors** with similar goals, although somewhat different capabilities. Humana's work with Cohere (see **Appendix E**) offered a good example of the solution the Steering Committee discussed. It features the ability to provide a "super-authorization" for certain orthopedic procedures based on a care pathway Cohere built using the American Academy of Orthopedic Surgeons protocols. The need for subsequent authorizations for services along the care pathway is waived if the clinician follows the prescribed protocol.

There are two issues with this approach. First, it will prove most effective for services for which vendors and their payer clients adopt protocols developed or endorsed by major provider associations; modifications of these based on individual payer preferences will create variation. As the Steering Committee had previously noted, agreement on protocols—for example, what constitutes accepted treatment for chronic conditions—was not entirely straightforward. Second, avoiding payer specific portals will increase interoperability and the use of standard data sets, however, further expansion of the HL7 and Da Vinci workgroup implementation standards for PA is necessary to address the latter issue, accompanied by vendors' willingness to use these. Recognizing these hurdles, the Steering Committee nevertheless endorsed this approach as contributing to incremental reductions in the need for multiple authorizations in an episode of care.

Substitute the use of clinical decision support mechanisms for payer PA. A similar solution involves embedding CDSMs in provider ordering processes. Providers who have executed payer contracts with financial risk have put some of these in place. The issue for payers is the extent to which providers can override the guidance in place. It is not clear the extent to which tools developed accommodate all fields, such as pediatric practices. Use of CDSMs may reduce the need for PA in some instances, but its impact is likely limited as it will remain dependent on individual provider/payer agreements for a relatively small number of services. Committee members seemed comfortable with having this option remain in the purview of the payer-provider contracting process.

The following solution addresses variation in the documentation required by payers to satisfy PA requirements.

Expand use of family/group codes. Providers strongly endorsed continued work by payers to group certain codes together so that approval for one CPT code could be considered to encompass approval for closely related codes. Progress against this goal seems to be a matter of inertia, rather than principled objection. Substituting this work for the push to standardize forms* might allow for forward momentum with positive consequences, as discussed further in our recommendations.

^{*}We must acknowledge that the work to develop standardized forms is required under Chapter 224 of the Acts of 2012 and cannot be substituted without a statutory change.

Recommendations

NEHI sets forth here a set of tailored action steps for pursuit in Massachusetts. We neither intend to foreclose further consideration of the reforms discussed above, nor of more detailed policy and practice recommendations that scholars and advocates continue to publish. Our recommendations rely heavily on the Mass Collaborative's willingness and ability to continue work to actualize these recommendations, as well as the HPC's creativity in achieving accountability for progress against them. We outline pathways through which the Mass Collaborative, HPC, and individual providers and payers may operate to carry out these recommendations. Based on our research and discussions, NEHI believes these recommendations are feasible, have considerable support, and impact important issues. We nevertheless note where Steering Committee member concerns were raised. The following principles guided us:

- 1. There are no perfect solutions, but we should move forward with solutions in which benefits outweigh concerns. Some of the action steps recommended garnered objections, but they can and should be overcome.
- 2. Time is of the essence. Prior authorization issues have been on the table for several years. Continued discussions without action will, for good reason, lead to regulatory proposals that will be blunter tools, prove less productive, and garner stakeholder resistance, which will in turn delay their intended impact.
- 3. There must, however, be some incentive to move forward, likely with both carrots and sticks. We are recommending, at a minimum, that HPC and DOI work deliberately and collaboratively with payers and providers, prioritize solutions, implement them, and seek to collect information to demonstrate progress.

A. Create Accountability for Clear Reform Priorities

The Steering Committee discussed reforms on which there was substantial consensus. We believe there is a way to ensure progress against these without legislation or regulation at this time if the HPC, in its convenor/policy leadership role, can work with payers and providers to clarify a limited number of priorities linked with specific outcomes. We recommend the HPC explore ways to achieve accountability for these outcomes in collaboration with payers and providers; the Mass Collaborative may volunteer to propose concrete next steps or act as a convener. Because this recommendation squarely places responsibility on payers to make incremental changes, we have set forth a few below on which we believe progress can be made relatively quickly. In each case, it is appropriate to monitor the impact of utilization changes associated with recommended reforms to engage providers in their success and sustainability.

- 1. Reduce the number of PAs associated with treatments for chronic conditions. Patient safety and delays in patient care must be balanced. Increasing adoption of care pathways and CDSMs would be one way to address this goal. Providers and patients should commit to sharing data that might inform additional reforms.
 - **a. The Mass Collaborative** should identify ways to reduce the number of PAs required for extended courses of treatment, especially those associated with chronic conditions, considering, for example, increasing the length of time between PA reviews, and/or increasing use of CDSM tools and care pathways. Bringing patients into this

- discussion would likely help identify focus areas.
- **b. The HPC** should work with payers and providers to scale identified options for modifying PA in connection with extended treatment protocols by publicizing successful reforms.
- 2. **Expand use of family codes**. Providers complained about administrative denials that are based on their failure (inability) to authorize the correct CPT code for a device or procedure in advance of certain treatments. They noted that claims are denied even when they have received approval for a CPT code that is related to the one for which authorization was received. Payers have begun to develop code groupings to address this issue.
 - **a. The Mass Collaborative** should identify options for services subject to PA that are affiliated with similar CPT codes and would benefit from an expanded approval range that includes like services and devices.
 - **b. The HPC** should request data on the scope of this issue. This would enable informed discussions with payers about policies they could adopt to clarify related codes and provide authorizations on this basis.
- 3. Align payers' medical necessity criteria for services subject to PA. Although automation will remove a good deal of the burden imposed by different medical necessity and documentation criteria,* variation in both continues to be a significant complaint for providers and patients. While there is some argument that payers distinguish themselves in deciding which services to subject to PA, the strategic advantage of imposing different medical necessity criteria seems more attenuated; indeed, payers readily adopt InterQual or Milliman standards when these are available. Setting a goal to reduce variation in medical necessity criteria for services for which third-party standards are not available would advance best practices without undercutting payers' discretion. The difficulty is in how to set a reasonable goal and then in how to achieve it.
 - **a. The Mass Collaborative** should work to identify variations in medical necessity criteria and documentation criteria where third- party standards are not used or are substantially modified, focusing especially on areas where denials are frequently associated with insufficient or incorrect documentation.† This would open the pathway to concerted work with professional societies to develop criteria for PA requests.
 - **b.** The HPC should ask providers and payers to offer recommendations on this point.

B. Charter a Task Force to Accelerate the Move Toward Automation

There is strong agreement that use of electronic PA and, more significantly, fully automated PA will reduce costs and alleviate provider frustration with the PA process, without impairing the benefits that PA confers. Automation is, however, a means to multiple ends, not an end on its own, and must be planned and evaluated with concrete goals in mind. For this reason, and in recognition of the resources that will be required to plan and support implementation efforts, we strongly recommend the formation of a task force (or working group) to develop specific recommendations and policies that provide a roadmap for the adoption of

^{*}Automation, in its most advanced form, will extract the necessary information from providers' EHRs based on a payer's specific medical necessity criteria. Theoretically, this will make providers impervious to variation in payer standards; information "automatically" retrieved from the EHR will correspond to a payer's specific documentation needs.

[†]The Steering Committee discussed establishing a forum for payers and providers to identify those services for which variation among payers has the largest impact on patients and providers (and for which payers must process the largest number of appeals). There was discomfort with this suggestion; members opposed a mandatory forum and there was concern about how openly work could or would be conducted given anti-trust concerns and possible inclusion of patients or employers.

automated PA processes by payers and providers in the Commonwealth. Without sufficient education and preparedness by payers, providers, IT vendors, and regulators, automation will not achieve its potential and will contribute administrative costs, rather than reduce them.

We recommend that such a task force be formally constituted by Executive Order in consultation with the Mass Collaborative and those involved in the MHDC and NEHEN pilot. The Task Force would be charged—within a specified time frame (e.g., nine months but further informed by the stakeholders above)—with issuing a multi-stakeholder report that would inform legislative and executive branch decisions and policies. The Task Force should study the operational requirements for automation, including fundamental issues regarding data sharing and uniformity, assess the varied capacity of payers and providers, propose possible actions to address gaps in readiness, and make recommendations for needed resources, as well as appropriate incentives and mandates.

NEHI (and MHDC) would be interested in working with the HPC and Mass Collaborative to establish a clear charter for the Task Force, its leadership, membership, and timeline, as well as facilitate the Task Force's work. It would identify resources necessary for the Task Force to produce actionable recommendations. HPC's involvement in crafting and appropriate Executive Order or other time-bound directive, is critical.

Share Data to Make Informed Decisions about PA

There was considerable agreement that publishing information (electronically) about the services subject to PA by payers doing business in the Commonwealth would be worthwhile. The Steering Committee found useful the data MGB made available to illustrate variation in payer policies (see **Appendix F**) even though this information is, for the most part, available on individual payer sites. Consolidation of the information more clearly identifies which plans require PA for which services* and, therefore, whether certain plans are outliers in their application of PA (either in commission or omission). The consolidated information will provide payers with a clearer understanding of variation, which may accelerate standardization or, possibly, reduction in PA. (Providers must accept the risk that plans may increase their scrutiny of certain services based on other plans' PA requirements and is likely an undesirable way to reduce variation). A consolidated format, importantly, would provide patients with a far simpler way to compare plans.

Because, as noted above, the technical challenges with upkeep of a consolidated site are real, we advise curbing ambition initially on any site established, (for example, foregoing publication of specific medical necessity criteria for PA, which could be made available on an individual payer's website). Concerns about providing updates in PA requirement changes could be addressed by clarifying the frequency with which the site is updated (ideally annually to start), alerting individuals to the need to verify the information provided, and embedding at least a general link to payers' websites. Such a website will be far easier to construct after payers upload PA requirements in connection with automation, but we suspect the website could be constructed by a third-party vendor under contract with the DOI and recommend

^{*}See similar recommendations in the AHA's 2020 report, "Addressing Commercial Health Plan Abuses to Ensure Fair Coverage for Patients and Providers".

that the DOI explore options for doing so, even with limitations. That said, the benefits are theoretical. Evaluating the utility of the site against any burden imposed on payers to maintain updates will be critical and evaluation criteria should be part of any effort.

There was some discussion about publishing information relating to the rate of denials overturned on appeal. Payers are required to report this data to various certifying and regulatory authorities, but data are not easily accessible in an internet search. There are at least six states that have taken steps to make information regarding the results of PA processes more transparent, including the number of PA approvals and denials and the reasons therefore.* Only two of these required disclosure of PA denials on a consolidated basis, rather than on individual payer websites only. We could not locate comments, formal or informal, on the impact of this legislation. Overall, continued efforts to increase transparency on the impact of PA would appear to highlight problematic practices, but discussions with states that have taken steps to make data publicly available would be helpful to evaluate whether the requirements are associated with changes in PA practices.

- **1. The Mass Collaborative** should work with its organizations' members to explore the most productive and feasible ways to share information about PA and its impact, perhaps through surveys or focus group discussions.
- **2. The HPC** should identify the technological resources necessary to maintain a public site. They should initially focus on consolidating information on the application of PA to services by payers conducting business in Massachusetts.

D. Pilot a Program to Target Outlier Practices

Several Steering Committee members have expressed an interest in exploring work with Dr. Martin A. Makary's company - Global Appropriateness Measures ("GAM"). As its name suggests, the company publishes measures of appropriate utilization, providing a range of acceptable practices based on research and provider consensus.† Payers and providers can define utilization thresholds and apply these to their own datasets for specific services within specialties. Health plans and providers can subscribe to the GAM consortium, through which they would receive access to a library of measures. They are also able to select certain specialties, without utilizing the full set of measures.‡ GAM is equipped to provide support in areas such as data analysis, threshold definition, and guidance to reduce inappropriate utilization. For example, GAM may prepare "Dear Doctor" letters,§ which they found successful in the reduction of variation and led to long-term behavior change. 102

†Over the past six years, Dr. Martin A. Makary and his team have conducted more than 1,000 interviews and focus groups with specialists across various fields of medicine to identify patterns of overuse in their area of expertise.

‡GAM's analyses also assist health plans in determining areas to target based on their networks' utilization patterns and potential economic benefits.

§Letters present unique service utilization data. The letters also identify the threshold within which providers should aim and show the recipient where they fall within the distribution.

^{*}Most states require beyond requiring publication of PA policies and criteria on individual payer websites. At least six states go beyond this. Arkansas requires PA approval and denial statistics be published on plan websites (AR §23-99-1104). Delaware passed HB 381 (2016) outlining similar transparency requirements that must be shared with the Delaware Health Information Network twice a year. The HPC and Office of Patient Protection in Massachusetts annually collect and report health plan information claims statistics, including medical necessity denials. Minnesota's Statue M.S.A. § 62M.17 requires health plans to post PA statistics on their websites by April 1 of each year, detailing the number of PAs, appeals, denials, and electronic PAs. These statistics are further subcategorized (e.g., service, reason). New Mexico's SB 188 (2019) requires plans to submit PA data to the governor and legislature by September of each year. Finally, Texas SB 1742 (2019) requires annual PA statistics on approvals, denials, and appeals.

It is important to note that GAM is a relatively new company, and its methodology is still being tested. Moreover, it targets practices that are not subject to PA. The GAM methodology and PA have similar aims, however, both seeking to avoid unnecessary or inappropriate care. Moreover, GAM's methodology seeks to identify physicians whose behavior is outside of practice norms. This parallels the concept behind gold-carding, which continues to apply PA to physicians whose practices do not fall within payer standards.

In discussions with Dr. Makary, he expressed interest in working with Massachusetts stake-holders to determine whether the GAM methodology may be used to reduce practice variation among physicians and thereby avoid the need for PA. Providers would like to determine whether they could agree to participate in the process of comparing their practices to established measures as a substitute for PA. This would require that measures of appropriate utilization be available for services currently subject to PA.

We recommend pursuing the possibility of a pilot involving GAM or similar methodology. NEHI has had preliminary discussions with at least one payer and a large health system that have expressed interest in pursuing discussions to formulate a pilot. They have made us aware that there is another company that performs services similar to GAM, relying on peer or social norms to change physician behavior. The pilot would test changes in utilization patterns for certain services that are now subject to PA to determine whether the GAM (or similar use of peer data) has the same impact as PA in changing utilization patterns. Comparing three randomized groups of physicians might prove most useful in assessing the impact of the methodology: physicians subject to PA for a given clinical service, physicians who participate in the GAM methodology but are not subject to PA, and physicians who remain subject to PA and also participate in the GAM methodology.* Depending on the pilot's outcome, GAM (or a similar methodology) could be used to reduce existing PAs and avoid additional PAs while improving evidence-based practices.

Planning is needed to identify potential participants, the pilot's scope, and feasible vendors, which in turn would help determine the pilot's cost.† NEHI could facilitate participants' engagement, scope definition, and project management, acknowledging that the details of the pilot must identify necessary system capabilities. NEHI would contract with a third party to plan and evaluate the pilot's outcome measures.

E. Pursue Tests of Change in Individual Contract Negotiations

Two options that could be tailored to provider performance include "gold-carding" and the waiver of PA in cases where providers assume substantial accountability for performance and quality measures. Both initiatives are dependent on the terms of specific contractual arrangements, but to the extent that HPC can provide a forum for sharing the outcomes of alternative or novel arrangements that modify PA terms, this may allow further adoption of reforms.

^{*}The details of a pilot would clearly require deep involvement from GAM and further discussion.

†We have only discussed a potential pilot on a preliminary basis with Dr. Makary. He has indicated some flexibility in discussing the cost of a pilot. Large payers engage GAM on a Per Member Per Month (PMPM) basis, but providers and payers have also subscribed to the library of measures that GAM has established, engaging GAM for varying analytic services.

- 1. Individual Payers and Providers should consider smaller initiatives as part of their contract negotiations, such as gold-carding and shifting responsibility for PA to providers or waiving PA based on assumption of financial risk and quality performance.
- 2. The HPC should request reports on innovative PA reform approaches and publish promising practices.

F. Requiring Multi-stakeholder Collaboration

The Vermont CURB offered a useful forum for important discussions between a single payer and providers in a smaller medical community. The complications of creating, much less mandating, a similar forum here are significant. If, however, payers and providers do not advance the recommendations made here in the next two years, it would be important to consider the creation of a Council to make recommendations on persistent, but clearly defined, issues and enforce continued dialogue. We believe anti-trust concerns can be overcome by executive order or legislation establishing parameters for the Council's activities.* We note that payers strongly oppose this recommendation, a recommendation NEHI made in writing this report without substantial Steering Committee input. We also note that there is nothing preventing payers and providers from pursuing such a forum voluntarily, as a venue for specific case studies or continued review of possible reforms.

Conclusion

Overall, this project met its goals and justified a relatively labor-intensive process. Of course, the true success of the project will depend on the extent to which the recommendations above are pursued. By providing limited, concrete suggestions, the project's sponsors—the Mass Collaborative and HPC—have a clear road map for next steps.

We also make the following observations about the project process. The Steering Committee was useful in both clarifying the issues related to PA and, more importantly, in enabling a discussion of opposing positions. While not all participants on the Steering Committee were equally engaged, we received multiple comments on draft observations and recommendations and believe that payer, provider, and patient perspectives were well-represented. The literature review and interviews provided important context, as well as a framework for analysis. NEHI believes that these elements helped broaden the perspectives of Steering Committee members; members' willingness to endorse compromise recommendations provides evidence of this. In general, however, all involved in this process noted the lack of quantitative evaluations of reform efforts.

The process did not alter some fundamental positions, but NEHI does not believe this is a barrier to productive forward momentum. We acknowledge that payers, which are essential to PA reforms, remain opposed to legislatively mandated changes. Respecting the reasons for this position—currently—the recommendations here largely avoid legislative or regulatory solutions. We are certain that payer energy would be directed at opposing these, which would detract from work that might yield voluntary changes in PA. We were encouraged (though optimism may be in play here), that in endorsing many of the recommendations in this report, payers recognized the need for reforms and the benefits that would accrue, especially in terms of approaches that continue to provide more efficient and effective UM.

For their part, providers continued to advocate for defined reductions in PA, especially in instances when rates of approval were above 95% or a similar threshold. That said, they came to appreciate the payers' objections. While provider representatives acceded to the focus on incremental changes in NEHI's recommendations, they are clear to believe a more forceful call to action is necessary. NEHI's advocacy for accountability and clear time parameters in connection with the action steps outlined are intended to address this.

Finally, we note that this project relied heavily on the Mass Collaborative. We must emphasize that the engagement of their members and leadership will remain critical if this report is to have value. We especially thank the Executive Committee, which provided detailed input and continued to discuss issues openly and productively. We urge the Mass Collaborative to advantage of the momentum created and take the lead in pursuing the recommendations here.

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Appendix A. Stakeholder Interviewees

Name	Corporate Affiliation	Industry Segment	Interviewed
Mil E I I G		D	4/00/0004
Mike Funk, Lisa Stephens	Humana	Payer	4/23/2021
Siva Namasivayam	Cohere	Payer/Vendor	4/29/2021
Barbara Spivak	Mount Auburn Cambridge IPA	Provider	5/5/2021
Mitchell Psotka	Inova	Provider	5/6/2021
Scott Strenio, Christine Ryan	Medicaid of Vermont	Payer	5/10/2021
David Cutler	Harvard University	Academics	5/13/2021
Kathy Gardner	Blue Cross Blue Shield of Mass	Payer	5/13/2021
Steve Pearson	Institute for Clinical and Economic Review	Academic/Non-Profit	5/13/2021
Hemant Hora	Harvard Pilgrim	Payer	5/19/2021
Craig Samitt	Blue Cross Blue Shield of Minnesota	Payer	5/28/2021
Mark Dichter	Fallon	Payer	6/4/2021
Kate Berry, Elizabeth Goodman	America's Health Insurance Plans	Payer	6/9/2021
Alain Chaoui	Private Practice	Provider	6/10/2021
Nicole Morgan, Tracey Shobert	CVS CareMark	PBM	6/11/2021
Darlene Rodowicz, Laurie Lamarre	Berkshire Health Systems	Provider, Payer	6/17/2021
Kerry Whelan, Jonathan Joyner	Shields	Payer	6/21/2021
Kevin Beagan, Rebecca Butler	Mass Division of Insurance	Payer	7/27/2021
Rebecca Schwartz	Atrius	Provider	7/30/2021
Alli Lees	eviCore	Payer/Vendor	8/3/2021

Appendix B. Steering Committee Participants

Name	Corporate Affiliation	Title
Caitlin Fitzgerald	Dana Farber Cancer Institute	Manager for Drug & Radiology Authorizations
Dave Delano	Mass Health Data Consortium	Director of Information Technology
Dr. Michael Sheehy	Reliant Medical Group	Chief of Population Health & Analytics
Dr. Jeffrey Meyerhoff	Optum	Senior Behavioral Health National Medical Director
Dr. Lakshman Swamy	MassHealth	Medical Director
Hannah Frigand	Health Care For All	Director, Education & Enrollment Services
Ira Klein	Health New England	VP & Chief Medical Officer
Jennifer Daley	Cigna	Senior Medical Director for New England
John Salzberg	UMass Memorial Health Care	SVP, Finance & Chief Revenue Officer
Karen Granoff	Mass Health and Hospital Association	Senior Director, Managed Care
Katherine Cardarelli	Atrius	Director, Navigator
Lisa Finston	Mass General Brigham	Director, Payor Operations
Liz Leahy	Mass Association of Health Plans	Chief of Staff, VP of Advocacy & Engagement
MaryBeth Remorenko	Mass General Brigham	VP, Revenue Cycle Operations
Michael Katzman	Blue Cross Blue Shield of Mass	Director, Public Government & Regulatory Affairs
Paul Nealey	Boston Children's Hospital	Director, Patient Financial Clearance
Sarah Morgan	Health New England	Assistant General Counsel
Shane Rawson	Blue Cross Blue Shield of Mass	Director, Inter-Plan Programs
Vasundhra Sangar	Associated Industries of Mass	Associate VP Government Affairs
Yael Miller	Mass Medical Society	Director, Practice Solutions & Medical Economics

Appendix C. Steering Committee Agendas

Steering Committee 1 - April 1 & 7, 2021 Introductions

Project purpose, scope & timeline

Project norms

Background literature review & Discussion

Wrap up & Next steps

Steering Committee 2 - June 9, 2021 Review

Discussion of key issues & Solutions

Break

Breakout sessions

Report out & Next steps

Steering Committee 3 - June 25, 2021 Affirm/Amend issue statements

Breakout sessions – consider & discuss solutions

Develop consensus &/or recommendations for final report

Wrap up & Next steps

Appendix D. Expanded Use of Family/Group Codes Current State: TUFTS Groupable Codes (Radiology)

Authorized CPT/HCPHCS Code	<u>Description</u>	Allowable Billed Groupings	Allowable Billed Groupings Description
33225	Cardiac Resynchronization Therapy (CRT)	33221, 33224, 33225, 33231	33221 - Insertion of pacemaker pulse generator only 33224 - Pacemaker of implantable defibrillator w/attachment to previously placed pacemaker or implantable defibrillator 33225 - Pacemaker or implantable defibrillator 33231 - Insertion of implantable defibrillator pulse generator only
33249	Implantable Cardioverter Defibrillator (ICD)	33230, 33240, 33249	33230 - Insertion of implantable defibrillator pulse generator only; w existing dual leads 33240 - Insertion of implantable defibrillator pulse generator only; w existing single lead 33249 - Insertion or replacement of permanent implantable defibrillator system
33208	Pacemaker Insertion	33206, 33207, 33208, 33212, 33213	33206 - Insertion new/replacement permanent pacemaker w transvenous electrode; atrial 33207 - Insertion new/replacement of permanent pacemaker w transvenous electrode; ventricular 33208 - Insertion of new/replacement of permanent pacemaker w transvenous electrode; atrial and ventricular 33212 - Insertion of pacemaker pulse generator only; existing single lead 33213 - Insertion of pacemaker pulse generator only; existing dual leads
70336	MRI Temporomandibular Joint	70336	70336 - MRI TMJ W/O Contrast
70450	CT Head/Brain	70450, 70460, 70470	70450 - CT Head W/O Contrast 70460 - CT Head W/ Contrast 70470 - CT Head W W/O Contrast
70480	CT Orbit	70480, 70481, 70482	70480 - CT Orbit/ IAC W/O Contrast 70481 - CT Orbit/ IAC W/ Contrast 70482 - CT Orbit/ IAC W W/O Contrast
70486	CT Maxillofacial/Sinus	70486, 70487, 70488, 76380	70486 - CT Max/Facial W/O Contrast & CT Sinus Complete W/O Contrast 70487 - CT Max/Facial W/ Contrast 70488 - CT Head and neck 76380 - CT Sinus Limited W/O Contrast
70490	CT Soft Tissue Neck	70490, 70491, 70492	70490 - CT Neck W/O Contrast 70491 - CT Neck W/ Contrast 70492 - CT W W/O Contrast Upper Extremity
70496	CT Angiography, Head	70496	70496 - CT Angiogram Head W W/O Contrast
70498	CT Angiography, Neck	70498	70498 - CT Angiogram Neck W W/O Contrast

70540	MRI Orbit, Face, and/or Neck	70540, 70542, 70543	70540 - MRI Orbit, Face, Neck W/O Contrast 70542 - MRI Orbit, Face, Neck W Contrast 70543 - MRI Orbit, Face, Neck W W/O Contrast
70544	MRA Head	70544, 70545, 70546	70544 - MRA Head W/O Contrast 70545 - MRA Head W/ Contrast 70546 - MRA Head W W/O Contrast
70547	MRA Neck	70547, 70548, 70549	70547 - MRA Neck W/O Contrast 70548 - MRA Neck W/ Contrast 70549 - MRA Neck W W/O Contrast
70551	MRI Brain	70551, 70552, 70553	70551 - MRI Brain W/O Contrast 70552 - MRI Brain W Contrast 70553 - MRI Brain W W/O Contrast
70551	MRI Internal Auditory Canal	70551, 70552, 70553, 70540, 70542, 70543	70551 - MRI Brain W/O Contrast 70552 - MRI Brain W Contrast 70553 - MRI Brain W W/O Contrast 70540 - MRI Orbit, Face, Neck W/O Contrast 70542 - MRI Orbit, Face, Neck W contrast 70543 - MRI Orbit, Face, Neck W W/O Contrast

Current State: HPHC Groupable Codes (Radiology)

Authorized CPT/HCPHCS Code	Description	Allowable Billed Groupings	Allowable Billed Groupings Description
70036	MRI Temporomandibular Joint	70336	70336 - MRI TMJ W/O Contrast
70450	CT Heat/Brain	70450, 70460, 70470	70450 - CT Head W/O Contrast 70460 - CT Head W/ Contrast 70470 - CT Head W W/O Contrast
70480	CT Orbit	70480, 70481, 70482	70480 - CT Orbit/ IAC W/O Contrast 70481 - CT Orbit/ IAC W/ Contrast 70482 - CT Orbit/ IAC W W/O Contrast
70486	CT Maxillofacial/Sinus	70486, 70487, 70488, 76380	70486 - CT Max/Facial W/O Contrast 70487 - CT Max/Facial W/ Contrast 70488 -CT Max/Facial W W/O Contrast 76380 - CT Sinus Limited W/O Contrast
70490	CT Soft Tissue Neck	70490, 70491, 70492	70490 - CT Neck W/O Contrast 70491 - CT Neck W/ Contrast 70492 - CT Neck W W/O Contrast
70496	CT Angiography, Head	70496	70496 - CT Angiogram Head W W/O Contrast
70498	CT Angiography, Neck	70498	70498 - CT Angiogram Neck W W/O Contrast
70540	MRI Orbit, Face, Neck	70540, 70542, 70543	70540 - MRI Orbit, Face, Neck W/O Contrast 70542 - MRI Orbit, Face, Neck W Contrast 70543 - MRI Orbit, Face, Neck W W/O Contrast
70551	MRI Internal Auditory Canal	70551, 70552, 70553, 70540, 70542, 70543	70551 - MRI Brain W/O Contrast 70552 - MRI Brain W Contrast 70553 - MRI Brain W W/O Contrast 70540 - MRI Orbit, Face, Neck W/O Contrast 70542 - MRI Orbit, Face, Neck W Contrast 70543 - MRI Orbit, Face, Neck W W/O Contrast
70544	MRA Head	70544, 70545, 70546	70544 - MRA Head W/O Contrast 70545 - MRA Head W/ Contrast 70546 - MRA Head W W/O Contrast

70547	MRI Neck	70547, 70548, 70549	70547 - MRA Neck W/O Contrast 70548 - MRA Neck W/ Contrast 70549 - MRA Neck W W/O Contrast
70551	MRI Brain	70551, 70552, 70553	70551 - MRI Brain W/O Contrast 70552 - MRI Brain W Contrast 70553 - MRI Brain W W/O Contrast

Appendix E. Initial Reform Categories Identified in Literature Scan

- **1. Waiving/modifying PA in value-based arrangements**. NEHI identified three models under which value-based contracts may be negotiated.
 - a. Population-based models. Under this structure, PA is waived for populations based on conditions or procedures. The provider assumes risk. For example, Blue Cross Blue Shield of Minnesota and the Mayo Clinic negotiated in 2018 a five-year contract (2019-2023) to waive PA for eye tumors and pediatric cancers. The contract includes an annual rate increase to the Mayo Clinic. In addition, the Mayo Clinic assumes downside risk if cost-of-care targets are not met. The contract also facilitated the creation of a collaborative governing board to evaluate coverage for emerging technologies and pharmaceuticals.
 - b. Pharmaceutical-based models. Under this structure, PA is waived for certain first-line formulary treatments. The drug manufacturer assumes financial risk. For example, Oklahoma Medicaid and Melinta Therapeutics negotiated a pharmaceutical-based model (implemented in 2018) under which Medicaid agreed to place oritavancin⁷⁹ on its formulary as a first-tier drug and waive PA based on the promise of cost savings. Melinta Therapeutics assumes risk if cost savings are not achieved or if costs increase due to utilization of the drug.
 - c. Episode-based models. Under this structure, PA is built for a certain episode of care (e.g., hospital stay, ED visit, etc.). The provider assumes financial risk.
- 2. Proactive PA. Incorporating PA early in the care process provides increased information at the point of care. This requires real-time pharmacy benefit checks, clinical decision support tools, and up-to-date patient information in electronic medical records. For example, CMS's Clinical Decision Support Requirement (testing extended through 2021) requires clinicians to document consultation with an approved clinical decision support mechanism for certain advanced imaging (e.g., CT, PET, MRI) to ensure reimbursement. The clinical decision support mechanism determines whether the order adheres to appropriate use criteria; practitioners' ordering patterns that do not comply are considered outliers and are subject to PA. Under a proactive PA model, providers receive approval for downstream tests/therapies for patients with certain diagnoses/treatments. For example, in 2021, Cohere Health announced an agreement with Humana Inc. to improve the PA process for musculoskeletal treatment across 12 states. Cohere claims its technology platform allows PA to approve services across an entire episode of care.
- 3. Gold-carding. Under gold-carding, PA is waived for clinicians for a certain time period if their PA are approved at a benchmarked level. For example, Vermont and Alabama Medicaid evaluate imaging requests over 18 months and require a ≤3% and ≤5% denial rate, respectively, to waive PA for providers over the course of the following year. Blue Cross Blue Shield of Nebraska evaluates providers over a 9–12-month period and requires a ≤6% denial rate. If providers meet this goal, they are subject to 12 months of automatic approval.
- 4. Automation. Automation is discussed in detail in the Literature Review section.

Appendix F. Variation in Payer Criteria and Submission Forms

CPT	Description	Summary	BCBS	НРНС	Allways	Tufts	Cigna	Fallon	Humana	Aetna	United	CCA	Unicare	ВМСНР
0154U	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C=T], p.S249C [c.746C=G], p.G370C [c.11108G=T], p.Y373C [c.1118A=G], FGFR3-TACC3V1, and FGFR3-TACC3V3), utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue	LAB	NI/PA	PA Required	PA/NC	PA Required	NI/PA	Req Vary/ Obtain PA	PA Required	No PA Re- quired	PA Required	NI/PA	NI/PA	PA/NC
0162U	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)	LAB	NI/PA		PA Re- quired	PA/NC	PA Re- quired	Req Vary/ Obtain PA	PA Re- quired	No PA Re- quired	PA Re- quired	NI/PA	PA/NC	PA/NC
0166U	Liver disease, 10 biochemical assays (α2-mac- roglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cho- lesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflam- matory activity, and steatosis with a summary interpretation	LAB	PA/NC	NI/PA	PA/NC	PA/NC	NI/PA	PA Required	NI/PA	No PA Re- quired	No PA Re- quired	NI/PA	NI/PA	PA/NC
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)	LAB	NI/PA	PA Required	PA Required	PA/NC	Req Vary/ Obtain PA	Req Vary/ Obtain PA	PA Required	No PA Re- quired	PA Required	NI/PA	PA/NC	PA/NC
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	Mid CY2020 Add	NI/PA	NI/PA	PA/NC	PA/NC	NI/PA	Req Vary/ Obtain PA	PA Required	No PA Re- quired	No PA Re- quired	NI/PA	NI/PA	NI/PA
19361	Breast reconstruction; with latissimus dorsi flap	INTEGUM ENTARY SYSTEM	PA Re- quired	PA Required	PA Re- quired	NI/PA	NI/PA	No PA Re- quired	NI/PA	No PA Re- quired	PA Required	NI/PA	NI/PA	No PA Re- quired

Bladder Cancer (Urothelial) Pathways

Patient Name:	Date of Birth;
Member Number:	Treatment Start Date:
Pathology:	Stage:
Line of Therapy:Neoedjuvant/Pre-OpAdjuvant/Post-Op	ECOG Performance Status: ICD-10 Code:
_1xt Line _2xd Line _3xd Line _3xd Line+ _Maint	Goal of Treatment;CurativeNon-Curative
Biomarkers/Characteristics: (select all that apply)	
Microsatellite instability:dMMR/MSI-HMSI-LNot reported	Platinum Resistant/Refractory?YesNoNot reported
NTRK Fusion:PositiveNegativeNot reported	
Neoadjuvant Therapy Clinical Stage II, III, or IV Without	Evidence of Metastases (cT2, cT3, cT4a, cT4b, M0)
CMV: cisplatin, methotrexate, and vinblastine 3 cycles	
Gemcitabine (Gemzar) and cisplatin 4 cycles	
Adjuvant Therapy Stage 0 (Ta, Tis) or Stage I After TUF	RBT* or Following Resection of Recurrent or Persistent Disease
BCG: bacillus calmette-guerin, intravesical	
Gemcitabine (Gemzar), intravesical (low-grade histology only)
Metastatic Disease First Line of Therapy (1st Line)	
Gemcitabine (Gemzar) and cisplatinf	
Metastatic Disease Second Line of Therapy (2nd Line)	
Gemcitabine (Gemzar)	
Paclitaxel	
Pembrolizumab (Keytruda)‡	
* TURBT: Transurethral resection of bladder tumor	
† In the setting of recurrent/metastatic disease, a substitution of carbople	atin for clapiatin will be considered a pathway option

Note: Pathways are independent of specific health plan medical policy coverage criteria. Health plan medical policy/clinical geodelines should be consulted to determine whether proposed services will be covered. Biosimilars of reference products listed are considered "on pathway." However, reimbursement for biosimilar products may be impacted by health plan specific formularies, medical policy and preferred product rules.



Last review: 7/28/2020 | Effective date: 11/18/2019

Appropriate.Safe.Affordable @ 2020 AIM Specialty Health 9000-0725

Pegfilgrastim Precertification Request (Neulasta®, Fulphila®, Nyvepria™, Udenyca®, Ziextenzo®)

Page 1 of 2
(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification Phone: 1-866-752-7021 FAX: 1-888-267-3277 For Medicare Advantage Part B: Please Use Medicare Request Form

Please indicate: Start of treatment: Start date Continuation of therapy: Date of		,			
Precertification Requested By:	last deadlient	Phone:		Fax:	
A. PATIENT INFORMATION		T Hone.		T &x.	
First Name:	Last Name:			DOB:	
Address:		City:		State:	ZIP:
Home Phone: Work Phone:		Cell Phone:		Email:	
-	Patient Height: in	ches or cms	Allergie		
B. INSURANCE INFORMATION	ducing		,		
Aetna Member ID #:	Does patient have other	coverage? Yes	□No		
Group #:	If yes, provide ID#:				
Insured:	Insured:				
Medicare: ☐ Yes ☐ No If yes, provide ID #:	Medir	caid: Yes No Ify	yes, pro	vide ID #:	
C. PRESCRIBER INFORMATION					
First Name:	Last Name:	(Che	ck one):	. M.D. D).O. N.P. P.A.
Address:		City:		State:	ZIP:
Phone: Fax:	St Lic #:	NPI#: D	EA #:		UPIN:
Provider Email:	Office Contact Name:			Phone:	
Specialty (Check one): ☐ Oncologist ☐ Hematologis					
D. DISPENSING PROVIDER/ADMINISTRATION INFO					
Place of Administration: Self-administration:		Specialty Pharmacy Other:			macy
E. PRODUCT INFORMATION Neulasta (pegfilgrastim) Nyvepria (pegfilgras Ziextenzo (pegfilgrastim-bmez)			Uden	ıyca (pegfilgra	astim-cbqv)
Dose:		tions for Use:			
F. DIAGNOSIS INFORMATION - Please indicate primal Primary Indication:		any ower where applicabl Other:	e.		
			proper	tification requi	nete.
G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests. For All Requests (clinical documentation required): Yes No Is the request for Fulphila, Nyvepria or Ziextenzo? Yes No Is the patient tried and failed treatment with Neulasta due to a documented intolerable adverse event (e.g. rash, nausea, vomiting)? Yes No Is the patient completing an existing chemotherapy regimen that requires current use of the requested medication to remain unchanged? If yes, indicate start date of chemotherapy regimen: / / Yes No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information? Yes No Is the patient tried and failed treatment with Udenyca due to a documented intolerable adverse event (e.g. rash, nausea, vomiting)? Yes No Is the patient completing an existing chemotherapy regimen that requires current use of the requested medication to remain unchanged? If yes, indicate start date of chemotherapy regimen: / / Yes No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information?					
Chronic Myeloid Leukemia → □ Yes □ No Will the requested medication be used	d to treat persistent neutrop	enia due to tyrosine kinaso	e inhibito	or therapy?	
Hairy cell leukemia → Yes No Will the requested medication be used for treatment of neutropenic fever following chemotherapy?					

GR-69391 (12-20)

Continued on next page

CLEAR FORM

MASSACHUSETTS STANDARD FORM FOR MEDICATION PRIOR AUTHORIZATION REQUESTS

*Some plans might not accept this form for Medicare or Medicaid requests.

This form is being used for:					
Check one:	☐ Initial Request	☐ Continuation/Renewal Request			
Reason for request (check all that apply):	☐ Prior Authorization, Ste ☐ Quantity Exception ☐ Specialty Drug ☐ Other (please specify):_	p Therapy, Formulary Exception			
Check if Expedited Review/Urgent Request:		attest to the fact that this request meets the for expedited review and is an urgent request.)			
A. Destination — Where this form is being submitted	to; payers making this form availa	ble on their websites may prepopulate section A			
Health Plan or Prescription Plan Name:					
Health Plan Phone:	Fax:				
B. Patient Information					
Patient Name:	DOB:	Gender: ☐ Male ☐ Female ☐ Unknown			
Member ID #:					
C. Prescriber Information					
Prescribing Clinician:	Phone #:				
Specialty:	Secure Fax #:	Secure Fax #:			
NPI #:		DEA/xDEA:			
Prescriber Point of Contact Name (POC) (if different than					
POC Phone #:	POC Secure Fax #:				
POC Email (not required):					
Prescribing Clinician or Authorized Representative S	ignature:				
Date:					
D. Medication Information					
Medication Being Requested:					
Strength:	Quantity:				
Dosing Schedule:	Length of Therapy:				
Date Therapy Initiated:					
Is the patient currently being treated with the drug requ	ested? 🗌 Yes 🔲 No 💮 If yes, o	date started:			
Dispense as Written (DAW) Specified?					
Rationale for DAW:					
E. Compound and Off Label Use					
Is Medication a Compound? Yes No					
If Medication Is a Compound, List Ingredients:					
For Compound or Off Label Use, include citation to peer	reviewed literature:				
	1	(continued on next pa			

 ${\it Massachusetts Collaborative -- Massachusetts Standard Form for Medication Prior Authorization Requests}$

April 2019 (version 1.0)

Appendix G. Steering Committee 3 Discussed Solutions

- **A.** Remove PA for certain services with high rates of approval (i.e., with denial rates < 3%). Steering Committee members expressed a high degree of consensus in principle. Plans maintain that they conduct regular reviews of services for which denials are rare, but they strongly oppose mandating removal of PA based on rates of prior authorization approval. They presented data demonstrating that removal of PA for physical therapy, for example, would increase utilization without offsetting reduction in the use of other services.*
- **B.** Remove multiple and repeat PAs for a continuous course of treatment. Examples of PA deemed unnecessary included authorization for repeat scans that are based on established treatment protocols, and extended drug treatments based on chronic disease regimens. Eliminating PA for services on a treatment path or protocol has been described elsewhere as proactive PA. The issue raised here was payers' confidence in the ongoing validity of a treatment course.
- **C. Create incentives for uptake of electronic PA**. There was broad consensus that electronic PA, although falling short of complete automation, would save significant processing time per transaction, as well as generate considerable savings (if used nationally, estimates are upwards of \$450M annually). Electronic solutions are indeed widely available. Nevertheless, uptake by providers and payers remains between 50-60%. Incentives, whether carrots or sticks, seem necessary.
- D. Remove PA for certain physicians based on their performance. As reported in our literature scan, "gold-carding" or performance-based PA waivers, have wide support—at least on an experimental basis. Support was less enthusiastic among Steering Committee participants in part because of the operational challenges associated with implementing the process (audits) and the failure of the process to alleviate physician office staff work (variation in gold card standards among payers may entitle physicians to a waiver for some plans and not others; need to distinguish among physicians for whom PA was waived and those who remained subject to PA processes). Participants agreed that further discussion was warranted.
- **E. Expand use of family/group codes**. There was broad consensus on the need for this solution; its ranking may reflect its more limited impact. Worth noting is data presented by one of the participants indicating that roughly 14% of authorized surgical procedures result in a denial due to lack of authorization for the associated medical device.
- F. Establish processes that require collaboration. Vermont Medicaid was the prompt for this solution, acknowledging its state-wide All Payer Model distinguishes it from other jurisdictions.† The Vermont Legislature tasked the Department of Vermont Health Access (DVHA) to create the Clinical Utilization Review Board (CURB) to examine existing medical services, emerging technologies, and relevant evidence-based clinical practice guidelines. Additional detail on the CURB can be found in the Literature Review section. Steering Committee participants were attracted to the notion of a multi-stakeholder group that discussed issues on a voluntary basis but were skeptical about what the group could accomplish. Past efforts to tackle cost issues with a coalition of voluntary stakeholders (e.g., Eastern Mass Health Initiative and Employer Action Coalition on Healthcare Administrative Complexity) provided informative dialogue but did not produce concerted action.
- **G.** Remove PAs for physicians in Accountable Care Organizations or risk-based arrangements. This solution also had widespread support in the literature but received less enthusiasm among Steering Committee members. Payers are hesitant to relinquish PA, which they regard as a fiduciary obligation to their members and clients unless or until providers assume substantial financial risk and demonstrate the capacity to pursue processes that replicate PA. Offering the PA delegation could be an option as systems do support case management which can implement these protocols. While some providers may not feel well equipped to handle PA processes internally, this could be determined as part of the contracting process and on a case-by-case basis.

^{*}This was based on a comparison between utilization rates in a PPO plan, which does not apply PA, and utilization in the less expensive HMO plan, which applies PA to physical therapy. The financial impact was significant.

[†]Vermont has a statewide Accountable Care Organization. As an incentive for providers to participate in the ACO, providers are exempt from most (but not all) prior authorization processes; ACO providers are not responsible for the costs of drugs. The CURB determines what PA processes to put in place for Medicaid providers generally.

- **H. Embed care pathways/utilization management on a condition basis**. This solution was seen as closely related to B above (Remove multiple and repeat PAs for a continuous course of treatment) and is one meriting additional consideration. Participants discussed newly available tools that allow providers to obtain authorization for care protocols by logging into portals with embedded care pathways. No further PA is required if the provider follows the pathway prescribed.
- I. Substitute payer PA with use of clinical decision support tools. If a provider agrees to utilize a clinical decision support tool that reflects payer criteria for PA approval, some payers waive PA for the relevant service. Most commonly this applies to imaging. This solution is often called point of care guidance. The extent to which providers can override the guidance provided is an issue for payers. Further study is warranted.
- J. Create economic incentives to reduce PA. David Cutler, a Harvard economist and member of the Health Policy Commission, has written convincingly about establishing separate pricing for claims that are subject to PA to reflect the true cost of the process. When PA is required, providers would be entitled to charge a higher price for the service. Payers would pay providers the additional cost for PA. This, in turn, would refine payer calculations regarding which claims need to fall under PA. Participants agreed with the concept but expressed concern about the added level of complexity it would add to difficult payer provider contract negotiations. Further research may be warranted.
- **K. Establish processes that incent collaboration**. This solution relies on making information about PA more easily accessible on the theory that exposure to facts about PA and utilization would provide incentives to reform PA requirements as well as reinforce effective PA. Decisions about scope as well as implementation challenges were cited hurdles to pursuing this solution.