

Abbreviated Analysis:

Analysis of California Assembly Bill 1107 Oncology Clinical Pathway Act of 2017

Summary to the 2017-2018 California State Legislature, April 14, 2017



AT A GLANCE

The version of California Assembly Bill (AB) 1107 analyzed by CHBRP would require a health plan or insurer that develops and implements a clinical pathway for cancer treatment, as defined, to comply with certain requirements. In addition, the bill would prohibit a plan/insurer from developing and implementing an oncology clinical pathway (OCP) that discourages patient access to clinical trials, requires provider use of the pathway or adherence to specific treatments therein, or interferes with the independent clinical judgement of a provider in patient care.

1. **Background.** Cancer is the second leading cause of death (after heart disease) in the U.S., with treatment costs of \$87.7 billion in 2014. An estimated 1.7 million individuals were expected to be diagnosed with cancer nationally in 2016, with 596,000 expected deaths. In California, about 173,000 new cases and 59,000 deaths were expected. To more effectively treat patients with cancer, many health plans/insurers and providers have begun to use oncology clinical pathways or OCPs. These have been defined by the American Society of Clinical Oncology (ASCO) as “detailed, evidence-based treatment protocols for delivering quality cancer care for specific patient populations, including the type and stage of disease,” that “balance the considerations of clinical efficacy, safety, toxicities, cost, and scientific advances.”
2. **Use of OCPs.** ASCO estimates that 60 health plans/insurers in the U.S. currently use OCPs, covering more than 170 million individuals. OCPs can be used for a variety of purposes in ways that are more flexible or more restrictive depending on implementation. CHBRP is aware of their use in educating providers and in offering financial incentives to providers for adherence to the recommended treatment sequence. Plans/insurers or providers can develop and implement their own OCPs, or purchase them from an external vendor. In 2016, several oncology pathway companies and at least one specialty benefits management organization were marketing OCPs to plans/insurers and providers for use in patient care.
3. **Approach.** AB 1107 does not mandate benefits for OCPs; rather, it establishes requirements for health plans/insurers who choose to develop and implement OCPs. There is no known evidence on outcomes, utilization, or costs associated with OCPs compliant with AB 1107 versus noncompliant OCPs; thus, CHBRP cannot conduct an evidence-based analysis on how health outcomes, utilization, or costs would be impacted by AB 1107. There is, however, some literature on plan/insurer and provider use of OCPs more generally. Although the focus of AB 1107 is health plans/insurers, the literature describing their use of OCPs is extremely limited (four studies). Thus, CHBRP also reviewed provider use of OCPs and identified 12 additional studies.
4. **Medical effectiveness.** CHBRP did not identify any studies of *health plan/insurer* use of OCPs that reported morbidity or mortality. However, CHBRP identified two studies examining the effects on emergency department (ED) and/or hospital use, which can be considered indicators of morbidity. These studies found that *plan/insurer* use of OCPs was associated with reductions in ED and hospital use, but CHBRP concluded that the evidence about effects on these outcomes is inconclusive because only one of these studies included a comparison group. In assessing the evidence on medical effectiveness for *provider* use of OCPs, CHBRP reviewed seven studies in the U.S., including one systemic review of 10 studies, but most did not have a comparison group. Therefore, it is uncertain whether changes in health outcomes could be attributed to *provider* use of OCPs. CHBRP concludes that there is limited evidence that *provider* use of OCPs improves some health outcomes, such as hospital length of stay, and does not decrease overall survival rates relative to usual care.
5. **Cost.** CHBRP identified and reviewed four studies of *health plan/insurer* use of OCPs that reported cost impacts. Due to weak study designs, however, CHBRP cannot conclude whether the costs reported in these studies were related to *plan/insurer* use of OCPs or other factors including baseline severity of disease. CHBRP concludes that there is insufficient evidence to assess the extent to which *plan/insurer* use of OCPs impacts costs. CHBRP reviewed three more recent studies of *provider* use of OCPs but, due to weak study designs, cannot conclude whether the lower reported costs were related to the use of OCPs or other factors including baseline severity of disease.

BILL SUMMARY

California Assembly Bill (AB) 1107 defines an oncology clinical pathway (OCP) as “a cancer treatment plan used by a provider to direct patient care for a defined patient or specific patient presentations, such as type or stage of the disease or for patients undergoing a specific procedure, that is used by the provider to make medical treatment decisions for the care of an enrollee or subscriber, in which the different tasks, interventions, or treatment regimens used by the provider are strictly defined and sequenced.”

AB 1107 would require health plans/insurers that develop and implement OCPs to do the following:

- Ensure that each OCP is evidence-based, clearly provides the level of scientific evidence supporting it, conforms to recommendations within the National Comprehensive Cancer Network (NCCN) for that disease, and is developed by a group of practicing physicians with relevant clinical expertise
- Review and update OCPs at least annually and as new therapies emerge
- Provide contracting providers information on OCP development including its scope; scientific data and evidence summaries evaluated; key clinical features and processes/rationales for decision making including quality, toxicity, and cost; names, qualifications, institutional affiliations, and conflicts of interest for individuals involved; and information on the process for review and updating the OCP

AB 1107 would prohibit health plans/insurers that develop and implement OCPs from doing the following:

- Discouraging patient access to clinical trials
- Requiring provider participation in an OCP or adherence to specific treatments therein
- Interfering with the independent clinical judgement of a provider in the care of a patient

The full text of AB 1107 can be found at the following link: [California Legislative Info](#). For this report, CHBRP has analyzed the bill language amended on March 21, 2017.

CONTEXT

In response to a request from the legislature to analyze AB 1107, Oncology Clinical Pathway Act of 2017, the California Health Benefits Review Program (CHBRP) prepared an abbreviated analysis that includes a review of the published literature and a summary of available information on the impacts of the use of OCPs. This report provides a definition of OCPs used by a professional society representing providers treating cancer and then summarizes the evidence about the effects of OCPs on medical effectiveness and costs. Because the research literature on plan/insurer use of OCPs is very limited, CHBRP also reviewed the literature on their use by providers (e.g., physician groups, hospitals).

BACKGROUND

Cancer is the second leading cause of death (after heart disease) in the U.S., with treatment costs of \$87.7 billion in 2014 (American Cancer Society, 2017). Expenditures on oncology drugs alone approached \$40 billion in 2015, with the price of some drugs exceeding \$150,000 per year (Beasley,

2017). An estimated 1.7 million individuals were expected to be diagnosed with cancer nationally in 2016, along with 596,000 expected deaths (American Cancer Society, 2016). In California, about 173,000 new cases and 59,000 deaths were expected. Due to the high prevalence of cancer and rapidly increasing costs of cancer treatment, and to more effectively treat patients with cancer, many health plans/insurers and providers have begun to use OCPs. OCPs are often designed to improve health outcomes through standardizing the care that clinicians or institutions provide to patients.

Definition and Use of OCPs

While there is general agreement in the published literature that clinical pathways incorporate considerations of clinical efficacy, safety, and costs, in that order, a more detailed definition of OCPs was developed by the American Society of Clinical Oncology (ASCO), a professional society representing over 40,000 physicians and other providers caring for people with cancer. ASCO defines OCPs as “detailed, evidence-based treatment protocols for delivering quality cancer care for specific patient populations, including the type and stage of disease,” that “balance the considerations of clinical efficacy, safety, toxicities, cost, and scientific advances.” (Zon et al., 2016)

There has been an increase in the use of OCPs by clinicians, payers, and other health organizations as a way to “improve patient care by limiting undesirable variability and reducing cost while providing for the optimal course of care for a patient’s specific diagnosis.” (Zon et al., 2016) An estimated 60 health plans/insurers in the U.S. currently use OCPs, covering more than 170 million individuals (Zon et al., 2016). A recent survey found that about 58% of oncology practices used OCPs in 2016 (ASCO, 2017).

In 2016, several oncology pathway companies and at least one specialty benefits management organization were marketing OCPs that plans/insurers and providers could implement for use in patient care. Examples of companies offering commercially available OCPs are listed below:

- [Cardinal Health's PathWare™ Pathways Management System](#)
- [eviti, Inc.](#)
- [McKesson's Value Pathways powered by NCCN™](#)
- [New Century Health](#)
- [Via Oncology](#)
- [AIM Specialty Health®¹](#)

Legislation on Clinical Pathways in Other States

CHBRP is aware of one other state, Connecticut, that has introduced legislation related to clinical pathways. During last year’s legislative session (2016), Senate Bill 435 was introduced with a focus on 1) requirements related to transparency of clinical pathways used by health carriers, and 2) supplemental provider payments for use of such pathways.² This bill shared many components of AB 1107. However, an amended bill authorizing a study of health carrier use of clinical pathways³ died in the state’s appropriations committee. In January 2017, Proposed House Bill 5960 was introduced and referred to

¹ AIM is a wholly owned subsidiary of Anthem, Inc. <http://aimspecialtyhealth.com/press-releases/2016/2016-04-13.php>

² Connecticut Raised Bill 435, February 2016: <ftp://ftp.cga.ct.gov/2016/tob/s/2016SB-00435-R00-SB.htm>

³ Connecticut Substitute Bill 435, February 2016: <ftp://ftp.cga.ct.gov/2016/tob/s/2016SB-00435-R01-SB.htm>

the Connecticut Joint Committee on Insurance and Real Estate; this bill establishes requirements for clinical pathways used by plans/insurers, including transparency and information on provider financial incentives.⁴ Both the 2016 and 2017 bills address clinical pathways more generally and are not focused on oncology.

Use of OCPs by State-Regulated Health Plans/Insurers in California⁵

In California, OCPs may be used in the care of enrollees in all plans regulated by the California Department of Managed Health Care (DMHC), including Medi-Cal managed care plans.⁶ However, AB 1107 does not appear to apply to policies regulated by the California Department of Insurance (CDI).⁷

For its 2016 analysis of AB 2209 (Clinical Care Pathways), CHBRP surveyed health plans and insurers regarding their use of clinical care pathways for cancer. Five plans/insurers indicated that they were not using OCPs, and the other seven did not respond.⁸

CHBRP is aware of only one large health plan/insurer in California that has “developed and implemented” OCPs,⁹ so that plan was surveyed regarding their use of OCPs this year. Representatives of that plan indicated that their OCPs: 1) summarize current evidence, 2) consider the factors outlined by ASCO (clinical efficacy, safety, toxicities, cost, and scientific advances), 3) are made available for voluntary use by providers and are not required, and 4) meet or exceed all but one of the transparency requirements of AB 1107. The one exception is in making the names of the practicing oncologists who develop the pathways publicly available; the plan stated that it lists the organizational affiliation for these oncologists but not their names to prevent their being contacted by others seeking to influence them. The plan stated that cost is the final factor considered in OCP development and that it is only considered in cases where other factors such as clinical efficacy, safety, and toxicity are equal among treatments. Representatives of this plan indicated that OCPs are being provided as an optional tool for providers and are not being used to determine whether to authorize or pay for treatment.

Two other plans with smaller market shares in California appear to purchase OCPs from external vendors.^{10,11} However, as the AB 1107 bill language refers to a plan/insurer that “develops and implements” an OCP, it is ambiguous as to whether the bill intends to include plans/insurers that simply “implement” OCPs that are developed by and purchased from an external vendor.

CHBRP is unaware of any plans/insurers in California implementing OCPs in any way that AB 1107 prohibits: 1) discouraging patient access to clinical trials, 2) requiring provider participation in an OCP or

⁴ Connecticut Proposed House Bill 5960, January 2017: <https://www.cga.ct.gov/2017/TOB/h/2017HB-05960-R00-HB.htm>

⁵ For estimates of enrollees in state-regulated health insurance, see CHBRP’s *Estimates of Sources of Health Insurance in California for 2017*, available at www.chbrp.org/other_publications/index.php.

⁶ Personal communication, R. Arnold, DMHC, April 4, 2017.

⁷ Personal communication, J. Figueroa, CDI, April 6, 2017.

⁸ CHBRP regularly surveys the largest (by enrollment) DMHC-regulated plans and CDI-regulated insurers in California and a sample of DMHC-regulated plans that enroll Med-Cal beneficiaries, as these plans/insurers provide the health insurance that may be subject to state-level benefit mandates.

⁹ AIM Specialty Health® (AIM) is implementing the Anthem Cancer Care Quality Program including enhanced reimbursement for initial diagnosis and for ongoing care that follows certain care pathways. For more information, see <https://anthem.aimoncology.com/>.

¹⁰ Aetna Selects New Century Health to Launch a National Program in Cancer Care Quality Management, Aetna press release, March 9, 2016.

¹¹ UnitedHealthcare Broadens Two of Its Oncology Management Programs, AISHealth, December 2015, 12(2).

adherence to specific treatments therein, or 3) interfering with the independent clinical judgment of a provider in the care of a patient.

IMPACTS

Approach to Analyzing the Impacts of the Use of Oncology Clinical Pathways

AB 1107 does not mandate benefits for OCPs; instead, it establishes requirements for plans/insurers who choose to develop and implement OCPs. Thus, an analysis of the impacts of AB 1107 would not examine the effects of an OCP benefit, but rather the effects of compliance with the requirements outlined in AB 1107. There is no known evidence on medical effectiveness, utilization, or costs associated with compliant versus noncompliant OCPs. Of the scientific literature that addresses OCPs, studies do not report sufficient detail on OCP development and implementation to assess whether these OCPs are compliant with AB 1107. Thus, CHBRP cannot conduct an evidence-based analysis on how health outcomes, utilization, or costs would be impacted by AB 1107.

There is, however, some literature on plan/insurer and provider use of OCPs more generally. CHBRP conducted a review of this literature to summarize the impact of the use of OCPs on health care outcomes including morbidity and mortality, as well as the impact on costs. CHBRP reviewed studies of OCPs that were implemented at the initiation of plans/insurers and at the initiation of providers. Studies were identified through searches of PubMed, the Cochrane Library, Web of Science, and the Cumulative Index of Nursing and Allied Health Literature. The search was limited to abstracts of studies published in English. Abstracts published from 2010 to the present were included.

Of the 408 articles found in the literature review, 26 were reviewed for potential inclusion in this brief, and 16 studies were ultimately included. The other articles were eliminated because they did not focus on the effect of OCPs on health outcomes, processes of care, or costs; were of poor quality as defined by the CHBRP protocol for evaluating the research literature;¹² or did not report findings from clinical research studies.

Evidence regarding the impacts of the use of OCPs on medical effectiveness and costs is summarized below. Their use by plans/insurers is described first, followed by their use by providers.

Evidence Regarding Medical Effectiveness of Oncology Clinical Pathways

Plan/Insurer Use of Oncology Clinical Pathways

OCPs can be used by health plans and insurers for a variety of purposes in ways that are more flexible or more restrictive depending on implementation. CHBRP is aware of their use in educating providers and in offering financial incentives to providers for adherence to the recommended treatment sequence. Although plan/insurer use of OCPs may have impacts on health outcomes, there is limited published literature assessing any such impacts.

CHBRP identified four studies regarding plan/insurer use of OCPs. The OCPs discussed in these studies were developed by health plans in partnership with oncology providers or a specialty oncology consulting group. All referenced using evidence-based guidelines in pathway development; one indicated that updates were issued on a quarterly basis (Feinberg et al., 2012).

¹² See Research Approach available at www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

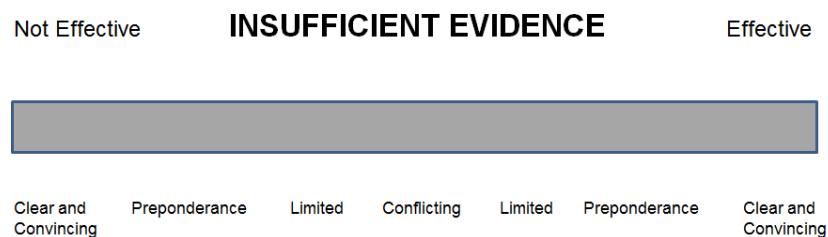
CHBRP did not identify any studies of the use of OCPs by health plans/insurers that reported morbidity or mortality. Two studies examined effects on emergency department (ED) and/or hospital use, which can be considered indicators of morbidity.

The first study used a retrospective, uncontrolled pre/post design to evaluate OCPs for breast, colon, and lung cancer in the first year of the program and five additional, unspecified malignancies in the second year. The OCPs were implemented by Blue Cross Blue Shield of Michigan (BCBSM) in partnership with Cardinal Health Specialty Solutions (Cardinal Health), which is a vendor of clinical pathways, and Physician Resource Management, a state physician organization. The authors reported that the use of OCPs was associated with lower rates of ED and hospital use (Feinberg et al., 2012). Although these findings suggest that implementation of OCPs by health plans/insurers improves health outcomes, the study did not include a comparison group. Without a comparison group, one cannot rule out the possibility that the reductions in ED and hospital use were due to other changes in care delivery that occurred at the same time that the OCPs were implemented. In a second retrospective study with a propensity-score matched comparison group that was conducted with CareFirst BlueCross BlueShield in the Mid-Atlantic region, the same investigators found use of pathways was associated with a reduction in the probability of hospital admission from 50% to 43% (Feinberg et al., 2013). The evidence of impacts on health outcomes for plan/insurer use of OCPs is summarized in Figure 1.

Figure 1. Plan/Insurer Use of Oncology Clinical Pathways: Health Outcomes Summary

Conclusion

CHBRP concludes that there is insufficient evidence regarding the effects of plan/insurer use of OCPs on morbidity and mortality based on two studies — one retrospective, uncontrolled study with a pre/post design and one retrospective study with a propensity-score matched comparison group.



Provider Use of Oncology Clinical Pathways

In addition to their use by health plans, OCPs can be used by providers for purposes such as education about best practices or for quality improvement. CHBRP assumed that unless studies specifically mentioned plan/insurer involvement in provider use of OCPs, plans/insurers were not involved. There is more published, peer-reviewed literature on provider use of OCPs than on plan/insurer use, but these studies typically focus on one specific component of health care for patients with a cancer diagnosis. For example, studies may focus on post-surgical care for persons who have had surgery to remove a cancer or on use of new medications or forms of radiation treatment for sub-groups of persons with cancer by persons who are likely to benefit from these treatments.

CHBRP found one systematic review (Gordon and Reiter, 2016) of 10 pre/post studies conducted in the U.S. that assessed provider use of OCPs for head and neck cancer surgery patients. This review found that nine studies reported statistically significant decreases in median/mean length of hospital stay.

CHBRP identified six more studies of OCPs implemented in the U.S. to treat persons with other types of cancer. One observational study found no difference in the percentage of patients who survived for 12 months following initiation of treatment (Neubauer et al., 2010). Another comparison study found that use of pathways was associated with a lower rate of chemotherapy-related hospital admissions, longer disease-free survival, and longer overall survival among persons with colon cancer (Hoverman et al., 2011). However, in both of these studies, patients in the comparison group appeared to be more severely ill than patients in the group treated per the OCP. Four pre/post studies assessed the impact of provider-developed OCPs (Jackman et al., 2017, Nussbaum et al., 2014, Rajagopalan et al., 2015, Rashid et al., 2016). Two of these studies reported improvements in processes of care and health outcomes (Rashid et al., 2016, Rajagopalan et al., 2015), and one found no difference in overall survival (Jackman et al., 2017). However, none of these four studies included a comparison group, so one cannot rule out the possibility that improvements were due to other changes that occurred at the same time that the OCP was implemented.

Many published studies on OCPs have been conducted outside the U.S. CHBRP found one meta-analysis that assessed randomized controlled trials (RCTs) conducted in China and Japan comparing use of pathways with usual care in patients with gastrointestinal cancers (Song et al., 2014). This study showed shorter average length of stay and higher patient satisfaction for patients treated using clinical pathways as compared with usual care. A prospective cohort study of patients in China found significant improvement in compliance with standard preoperative care processes in the cohorts treated according to pathways (Bao et al., 2016). Three uncontrolled cohort studies conducted in European countries reported increases in survival and reductions in complications and length of stay (Jensen and Maina, 2015; Preston et al., 2013; Richter-Ehrenstein et al., 2012).

In summary, CHBRP found limited evidence that provider use of OCPs improves outcomes, such as hospital length of stay, for persons with cancer and does not decrease overall survival rates relative to usual care. Although 16 studies have been conducted in the U.S., the strength of the evidence they provide is limited because most of them do not include a comparison group; thus, one cannot rule out the possibility that changes observed were due to other changes that occurred at the same time the OCP was implemented.

Evidence Regarding Costs Associated with Oncology Clinical Pathways

Plan/Insurer Use of Oncology Clinical Pathways

As noted above, AB 1107 establishes requirements for OCPs but does not mandate a specific benefit. CHBRP is unable to identify to what extent health plans/insurers would develop and implement OCPs that are or are not compliant with AB 1107; estimate provider behavior in response to OCPs that are/are not compliant with AB 1107; or define relevant population segments that would be impacted by AB 1107. Therefore, CHBRP is unable to analyze costs associated with the implementation of AB 1107.

Regarding the evidence on costs associated with the use of OCPs more generally, all four studies describing plan/insurer use of OCPs noted above also addressed changes in costs. These studies were conducted by two lead investigators (Feinberg et al., 2012; Feinberg et al., 2013; Kreys et al., 2013; Kreys et al., 2014) and examined OCPs developed by Cardinal Health in partnership with two Blue Cross Blue Shield plans. All studies were limited to populations with breast, lung, or colorectal cancer, and all studies examined costs in the first two years of OCP implementation.

Three studies used a pre/post design with no comparison groups (Feinberg et al., 2012; Kreys, 2013; Kreys, 2014). The first study (Feinberg et al., 2012) did not document actual costs but rather reported changes in utilization as identified through claims data. The authors reported that the use of an OCP

reduced variation in chemotherapy regimens, conversion from brand drug regimens to generic regimens when equally effective, and conversion from more expensive to less expensive brand drug regimens (Feinberg et al., 2012).

In the second study (Kreys et al., 2013), the authors did not examine changes in total costs associated with the OCP. Instead, the authors examined costs for specific types of services: drug costs related to supportive care increased \$631, whereas per-patient hospitalization costs decreased from \$2,502 to \$1,604. Total per-patient drug costs increased but were not statistically significant. The same investigator then focused on the impact of the use of OCPs on costs associated with specific types of supportive care therapies and found that use of a pathway for one type of medication, granulocyte colony stimulating factor (G-CSF), was associated with an average decrease of \$1,085 in costs for ED visits/hospitalizations, whereas the use of a pathway for other medications (erythropoiesis-stimulating agents and anti-emetic agents) was associated with cost increases of \$60 and \$7, respectively (Kreys et al., 2014).

None of these three studies included a comparison group; thus, one cannot rule out the possibility that the observed changes were due to other factors that occurred at the same time as OCP implementation, and/or due to the selection of motivated providers who were already interested in reducing costs of care. In the fourth study (Feinberg et al., 2013), the authors conducted a retrospective study with a propensity-score matched comparison group of patients; they estimated 15% cost savings associated with OCP use in the first nine months after initiation of chemotherapy.

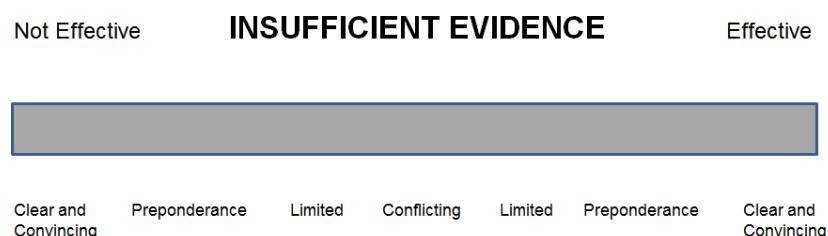
Because these studies addressed OCPs developed by one research group working with two plans/insurers, were limited to only three conditions, and only one included a comparison group, the results may not be generalizable to plans/insurers in California.

CHBRP did not find any more recent studies reporting cost results for these plans/insurers or any other plan/insurer in the published literature. The evidence of cost impacts when plans/insurers use OCPs is summarized in Figure 2.

Figure 2. Plan/Insurer Use of Oncology Clinical Pathways: Cost Summary

Conclusion

There is insufficient evidence to assess whether plan/insurer use of OCPs does/does not affect costs based on one retrospective study with a comparison group and three pre/post studies with no comparison group. OCPs used by health plans/insurers may affect costs, but the available evidence is insufficient to draw conclusions.



Provider Use of Oncology Clinical Pathways

There are also few studies that address costs associated with provider use of OCPs. In the systematic review on head and neck OCPs, researchers identified six studies that examined costs; however, all were

conducted in the 1990s (Gordon & Reiter 2016). Given weak study designs and studies completed long before the recent large increases in oncology costs and utilization, one cannot conclude from these studies whether provider use of OCPs for head and neck cancers affects costs.

CHBRP identified three more recent retrospective studies on the Level I Pathways program developed and implemented by the U.S. Oncology Network, a national physician oncology group.¹³ In the two studies that compared costs for patients treated on- versus off-pathway, both found lower costs for patients treated on-pathway (Hoverman et al., 2011; Neubauer et al., 2010). However, in both studies, the patients were not selected at random, and off-pathway patients appeared to have more severe/advanced disease (i.e., costs would be expected to be higher for these patients). The third study also found a reduction in costs associated with the use of OCPs but did not include a comparison group (Jackman et al., 2017).

In summary, due to weak study designs, CHBRP cannot conclude whether the lower reported costs were related to provider use of OCPs or other factors including baseline severity of disease.

Discussion

As various stakeholders in the health care system continue to engage in efforts to improve quality, reduce treatment variability, and manage the increasing costs of cancer care, there may be increased use of OCPs designed to achieve these goals. However, documentation in the published literature of the impacts of *plan/insurer* use of OCPs is quite sparse with CHBRP determining that there was insufficient evidence to assess impacts on either health outcomes or cost. Only limited evidence was found showing improvements in health outcomes when *providers* use OCPs; there was insufficient evidence to assess impacts on cost. As noted, these studies do not address outcomes specific to AB 1107, i.e., whether there are differences in outcomes or costs related to OCPs that meet the standards outlined by AB 1107 versus OCPs that do not meet these requirements. Thus, CHBRP can only offer conclusions on outcomes related to the use of OCPs more generally, not on the impacts of AB1107.

Several additional considerations related to the development and implementation of OCPs in compliance with AB 1107 merit mention. The first relates to the fact that provider groups typically contract with multiple plans/insurers, each of which may have its own OCPs. Use of any given OCP may be driven by its perceived usefulness/value from the provider's perspective as well as the proportion of their practice enrolled in that specific plan/insurer; a provider group that contracts with many plans/insurers may find that a given OCP pertains to only a small proportion of its patients. An OCP selected and implemented by a group of providers (rather than plans/insurers), by contrast, has the potential to be consistently implemented for all patients in the practice or group for whom the OCP is applicable.

A second issue relates to administrative costs that plans/insurers may incur to ensure that their OCPs meet the requirements of AB 1107. In addition to costs associated with meeting any of the bill's requirements of what they must do, it may be costly (and challenging) for plans to show that they are not, for example, discouraging patient participation in clinical trials or interfering with the clinical judgment of providers.

Third, there is a definition of OCPs available from ASCO; AB 1107 incorporates some aspects of this definition but not all and includes other aspects not in ASCO's definition. As a result, assessment of future compliance with AB 1107 by plans/insurers may be more challenging using the bill's definition of OCPs rather than ASCO's definition.

¹³ Since the publications of these studies, the Level I Pathways program has been acquired by McKesson.

Finally, CHBRP is unaware of any plans/insurers in California implementing OCPs in any way that AB 1107 prohibits: 1) discouraging patient access to clinical trials, 2) requiring provider participation in an OCP or adherence to specific treatments therein, or 3) interfering with the independent clinical judgment of a provider in patient care.

REFERENCES

- American Cancer Society. *Cancer Facts & Figures 2016*. Atlanta: American Cancer Society; 2016.
- American Cancer Society. *Economic Impact of Cancer*. Last Revised: January 23, 2017. Available at: <https://www.cancer.org/cancer/cancer-basics/economic-impact-of-cancer.html>. Accessed April 5, 2017.
- American Society of Clinical Oncology (ASCO). *State of Cancer Care in America, 2017: A Report by the American Society of Clinical Oncology*. Journal of Oncology Practice; published online ahead of print, March 22, 2017.
- Bao H, Yang F, Su S, et al. Evaluating the effect of clinical care pathways on quality of cancer care: analysis of breast, colon and rectal cancer pathways. *Journal of Cancer Research and Clinical Oncology*. 2016;142:1079-89.
- Beasley, D. The cost of cancer: New drugs show success at a steep price. *Reuters*. April 3, 2017.
- Feinberg BA, Lang J, Grzegorczyk J, et al. Implementation of cancer clinical care pathways: A successful model of collaboration between payers and providers. *American Journal of Managed Care*. 2012;18(5):e194-9.
- Feinberg BA, Milligan S, Cooper J, et al. Third-party validation of observed savings from an oncology pathways program. *American Journal of Managed Care*. 2013;19(spec no. 4):153-7.
- Gordon SA and Reiter ER. Effectiveness of critical care pathways for head and neck cancer surgery: A systematic review. *Head & Neck*. 2016;38:1421-7.
- Hoverman JR, Cartwright TH, Patt DA, et al. Pathways, outcomes, and costs in colon cancer: Retrospective evaluations in two distinct databases. *Journal of Oncology Practice*. 2011;7(suppl 3):52s-59s.
- Jackman DM, Zhang Y, Dalby C, et al. Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients With Stage IV Non-Small-Cell Lung Cancer. *American Society of Clinical Oncology*. 2017; published online ahead of print at jop.ascopubs.org on March 4, 2017.
- Jensen KH, Maina PJ. Cancer pathways are associated with improved long-term survival. *Danish Medical Journal*. 2015;62(2):A5000.
- Kreys ED, Kim TY, Delgado A, Koeller JM. Impact of cancer supportive care pathways compliance on emergency department visits and hospitalizations. *Journal of Oncology Practice*. 2014;10:168-73.
- Kreys ED and Koeller JM. Documenting the benefits and cost savings of a large multistate cancer pathway program from a payer's perspective. *Journal of Oncology Practice*. 2013;9: e241-7.
- Neubauer MA, Hoverman R, Kolodziej M, et al. Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. *Journal of Oncology Practice*. 2010;6(1):12-8.

- Nussbaum DP, Penne K, Speicher PJ, et al. The role of clinical care pathways: An experience with distal pancreatectomy. *Journal of Surgical Research*. 2014;190:64-71.
- Preston SR, Markar SR, Baker CR, et al. Impact of a multidisciplinary standardized clinical pathway on perioperative outcomes in patients with oesophageal cancer. *British Journal of Surgery*. 2013;100:105-12.
- Rajagopalan MS, Flickinger JC, Heron DE, Beriwal S. Changing practice patterns for breast cancer radiation therapy with clinical pathways: An analysis of hypofractionation in a large, integrated cancer center network. *Practical Radiation Oncology*. 2015;5(2):63-9.
- Rashid OM, Pimiento JM, Gamenthaler A, et al. Outcomes of a Clinical Pathway for Borderline Resectable Pancreatic Cancer. *Annals of Surgical Oncology*. 2016;23:1371-9.
- Richter-Ehrenstein C, Heymann S, Schneider A, Vargas Hein O. Effects of a clinical pathway 3 years after implementation in breast surgery. *Archives of Gynecology and Obstetrics*. 2012;285:515-20.
- Song X, Tian J, Cui Q. Could clinical pathways improve the quality of care in patients with gastrointestinal cancer? A meta-analysis. *Asian Pacific Journal of Cancer Prevention*. 2014;15:8361-6.
- Zon RT et al. American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology. *Journal of Oncology Practice*. 2016;12(3):261-7.

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Please direct any questions concerning this document to:

**California Health Benefits Review Program
University of California, Office of the President
UC Health
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org**

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from multiple University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

Garen Corbett, MS
Director