Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

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March 18, 2010

Commonwealth of Pennsylvania
House of Representatives Insurance Committee
Harrisburg, Pennsylvania 17120

ATTN.: Honorable Anthony M. DeLuca, Chairman

Re: Testimony in support of House Bill No. 1865 - Oncology Parity

Gentlemen:

The Community Oncology Alliance (COA) is a non-profit organization dedicated solely to community oncology. COA was founded by community oncologists to advocate for patients and providers in the community oncology setting, where over 80 percent of Americans with cancer are treated.

We respectfully request your favorable consideration of House Bill No. 1865 – Oncology Parity, currently being debated. Leveling the playing field by ensuring parity for all cancer drugs is sorely needed. We note, however, some potential language issues with the bill; shortfalls that may cause unintended consequences in patient out-of-pockets and therefore suggest the inclusion of the language below:

> ***A patient's out of pocket costs related to coverage for orally administered chemotherapy shall be on a basis no less favorable than coverage provided for intravenously administered or injected chemotherapy.***
>
> ***A health insurer cannot achieve compliance with this section by imposing an increase in patient out of pocket costs with respect to intravenously administered or injected chemotherapy agents covered under the policy on the effective date of this act.***

We have learned that House Bill No. 1865 bears some resemblance to legislation that was unanimously approved in 1989 known as SB 472. Both of these bills mandate equal coverage for cancer care, regardless of the setting for treatment. Now granted, in 1989 the prevalence of oral medications to treat cancer were rare; however, treatments in the community versus the hospital setting were becoming more commonplace, hence the need for this legislation. Today, however, there are now 37 oral oncolytics available to cancer patients receiving therapy in yet a somewhat new setting; the domicile. And, while the home may appear, on the surface, to be an ideal setting for treatment, it has become less so because of the cost prohibitive nature of an oral cancer medication and its coverage shortfalls under the prescription benefit of an insurance policy.

COA has just completed a research project focusing on barriers to accessing oral therapies. The study documents serious access and compliance issues associated with oral oncolytics, with cost being the primary barrier. The data studied consisted of over 5,000,000 prescriptions for over 500,000 patients from January 2007 through June 2009. The statistics revealed were astounding. Over twenty-one percent of oral oncolytic claims were rejected. Another nine percent were reversed and approximately twenty-five percent of patients had

no apparent follow-up after reversal of their original prescription of an oral oncolytic. Please note, by definition, a reversal is defined as an approved prescription, adjudicated through an insurance carrier, which has not been dispensed. In other words, the patient's prescription is approved, filled and never actually picked up by the patient. This quantitative study demonstrated to COA the importance of the continuum of care; care which is being delayed or in fact, never begun. In delving deeper into the actual plan formularies and noting where cancer drugs were placed, it became immensely clear that most, if not all, were on higher plan tiers equating to increased out of pocket patient costs. The rule of thumb is that any drug over $500. to $600. is placed on a higher tier equating to a higher cost sharing.

In 2010, most Prescription Drug Plans (PDPs) use formularies with four or more tiers. Most Medicare Advantage PDPs use formularies with four or more tiers. And further, PDPs generally use coinsurance on high tier formularies meaning, that in addition to their copay, patients will also have to pay a percentage of the cost of the drug; in essence, double dipping. This high dollar out of pocket is forcing cancer patients to go home and do nothing which, down the road, will cost the healthcare system even more dollars when the patient presents in the Emergency Room in dangerously poor health.

We must remember that neither patients, nor their physicians, have any control over the cost of needed medication. A typical cost share per month for a patient taking Revlimid for Multiple Myeloma is $1,400.00. Providers have routinely relied on pharmaceutical manufacturers and foundations to assist patients with their medications, but this system is less than ideal. Foundation support is not always there month-to-month and the ability of oncology practices to do the work for the patient is becoming overwhelming. Today's economy has caused an increase in uninsured and underinsured patients and that volume has forced many to go without treatment.

Now, insurance companies may testify that putting oral cancer medications on par with infusible and injectible therapies will cause employer premiums to rise. We do not pretend to have a pat answer for this, but we note that private insurers appear to be quite profitable. Why then must the pressure of increased premiums and out of pockets always be put upon the backs of employers and patients? Could we perhaps look for other solutions besides the annual rise in premiums? Perhaps a catastrophic out of pocket maximum would be a potential solution. The ability of oncologists to dispense orals within the walls of their oncology clinics, as they do infusibles, demonstrating not only efficient cost controls and patient management, but also better outcomes equating to fewer dollars spent in healthcare is another potential solution.

With more than 25% of the drugs in the cancer pipeline in an oral formulation, it is imperative that a clearly delineated statement of coverage be put into place, allowing cancer patients' access to the best form of treatment appropriate for their individual need. Ensuring parity for patient cost sharing for oral and IV cancer treatments will only increase access to and thereby improvement in the care and quality of life for cancer patients. In many instances, this will allow a patient a more expedient re-entry into the workforce, thus removing the burden from the State Medicaid roles, Unemployment Compensation Board, disability insurance, et cetera.

We hereby implore the Commonwealth of Pennsylvania legislature to urgently pass House Bill No. 1865 and to include in such legislation the above referenced amended language, so as to avoid unintended consequences.

COA welcomes the opportunity to provide further education and insight into this extremely important aspect of cancer care and we thank you for your consideration in this critical area.

Very truly yours,

Mary Kruczynski
Director of Policy Analysis
Community Oncology Alliance

ORAL ONCOLYTICS

Parity Legislation; House Bill No. 1865

Commonwealth of Pennsylvania

Hershey Medical Center

March 18, 2010

Mary Kruczynski,

Director of Policy Analysis

COA Mission

- Founded by Community Oncologists for Community Oncology
- Accessible, Affordable, Quality Cancer Care for all Americans
- 80% of cancer care delivered in community setting
- Most advanced cancer delivery system in the world

Background

- 37 different oral oncology agents are available in the U.S.
- Per NCCN, about 25% of the roughly 400 agents currently in the drug development pipeline are oral oncolytics
- Current challenges not only include patient selection for oral versus infusable, but also associated cost sharing, formulary, payer restrictions, pre-authorization, patient compliance, management and long-term care

The Route of an Oral Script for Lenolidamide (Revlimid)

Time=minutes

■ Physician decision making and patient discussion	20-30 min
■ Restricted distribution program: RevAssist	30-60 min
-Mandatory counseling -Register patient online, wait for form to be faxed -Complete and fax back patient-physician agreement form -Complete patient phone survey -Complete prescriber phone survey	
■ Prescription process -contact RevAssist contract pharmacy -Either pharmacy or office fill out prior authorization -Payment assistance programs to handle co-pay	>30 min

- Average time to get drug to patient 2-7 days
- Average co-pay per month - $1400.00

**Adapted from information provided by Theresa M. Mulvey, MD and the Celgene website*

37 Oral oncolytics and one drug for ITP

Breast cancer
- Capecitabine/Xeloda
- Lapatinib/Tykerb
- Letrozole/femara
- Anastrazole/arimidex
- Exemestane/aromasin
- Nolvadex/tamoxifen
- Fareston/toremifine
- Estradiol
- Cyclophosphamide/cytoxan
- methotrexate(not oral)

GI
- Capecitabine/xeloda

Lung cancer
- Erlotinib/tarceva
- *Gefitinib/Iressa(drug off the market for all intents and purposes)*
- Topotecan/hycamtin
- VP-16/etoposide

Ovarian
- VP-16/etoposide

Glioma
- Temozolamide/temodar
- Ccnu/lomustine

Multiple myeloma
- Lenalidomide/revlimid
- Thalidomide/thalomid
- Melphalan/alkeran
- Cyclophosphamide/cytoxan

Dexamethasone/Decadron

AML
- All trans retinoic acid/ATRA
- 6-mercaptopurine/6-MP
- Methotrexate (oral methotrexate not used in AML)

CML
- Hydroxyurea/Hydrea
- Imatinib/Gleevec|
- Nilotinib/tasigna
- Dasatinib/sprycel

CLL
- Chlorambucil/Leukeran

BMT
- Busulfan/myleran

Renal cell
- Sunitinib/sutent
- Sorafenib/nexavar
- Pazopanib/votrient
- Everolimus/afinitor

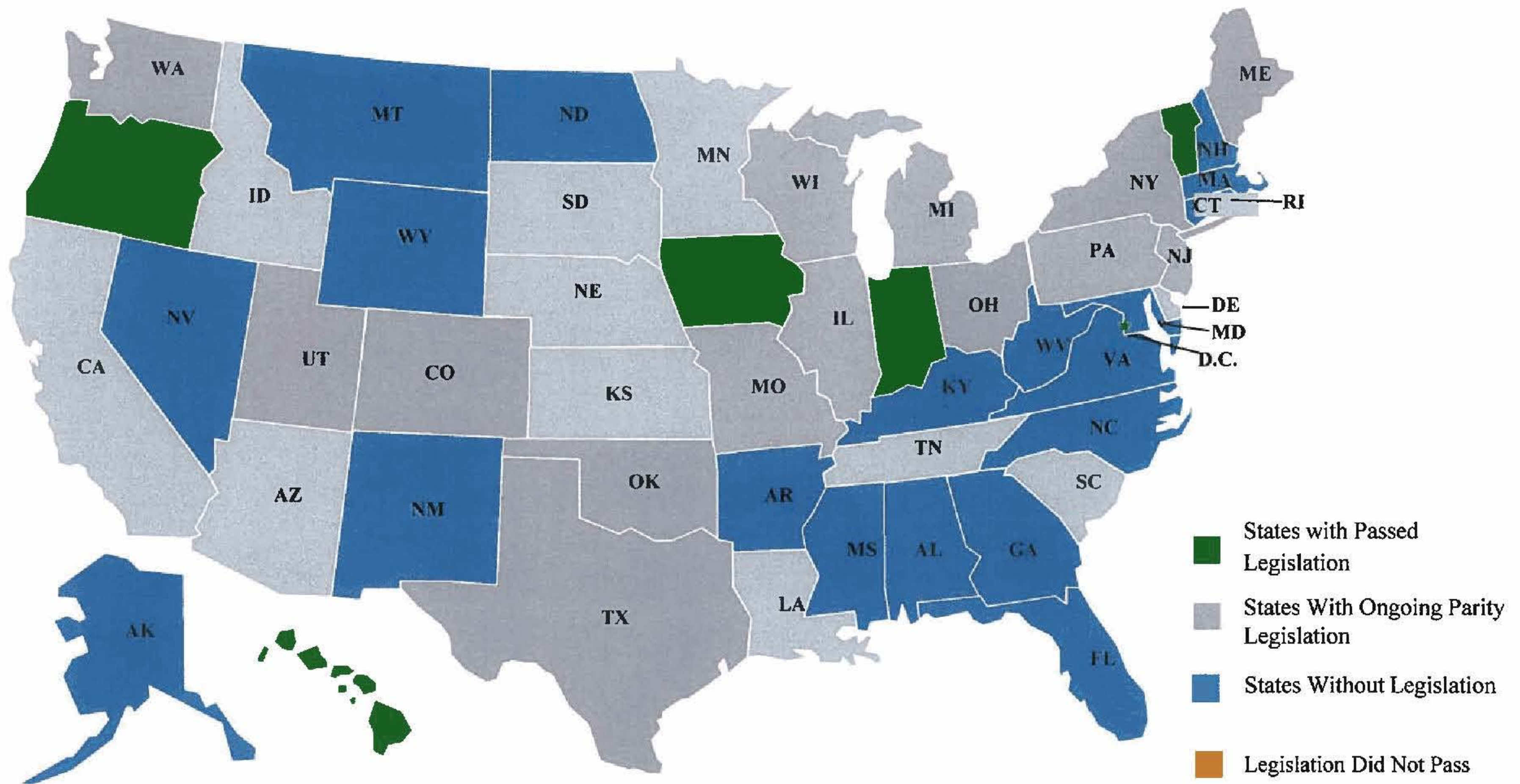
Prostate cancer
- Bicalutamide/casodex
- Ketoconazole
- Diethylstilbesterol

Cutaneous T cell lymphoma
- Baroxetene/Targretin
- Vorinostat/zolinza

Neuroendocrine carcinoma
- Sunitinib/sutent

ITP
- Eltrombopag/Promacta

Several States Are Moving Towards Parity For Oral and IV Oncolytics



Stark Similarities 1989 - 2010

- SB 472 – Unanimous approval 1989
- HB 1865 – Will history repeat in 2010?
- Several Members in the House then and now voted for this legislation
- Then.....
  - Equal coverage for cancer care regardless of setting

  Now........
  - Equal coverage for cancer care regardless of formulation of medication

Cancer Drug Coverage Parity Act

- Introduced May 12, 2009 by Congressman Brian Higgins (NY-27)Ways & Means Committee member
- A bill to require health insurance coverage for intravenous/injectable and orally-administered cancer pills at the same rate
- *Coverage has not kept up with quickening pace of scientific discoveries and cancer patients paying the price (Congressman Higgins)*

COA Orals Project Overview

- Objectives:
  - Assess the existing community oncology environment for oral oncolytics
  - Catalog barriers to access for oral oncolytics
  - Identify opportunities for engagement with key stakeholders
  - Develop strategies to improve access to oral oncolytics
  - Capture best practices for providing optimal cancer care using oral oncolytics

Oral Oncolytics Present a Wide Range of Challenges for Community Oncologists

- Orals project explored how these challenges impact the day to day operations of community oncology practices
- Many crucial functions related to a patient's treatment regimen are not reimbursed
- While oral agents are often preferred by patients, it is often more difficult to manage side effects and compliance
- Inconsistent payer approaches to the management of oral agents cause confusion and administrative burden for both patients and providers
- Lack of parity for orals vs. infusables

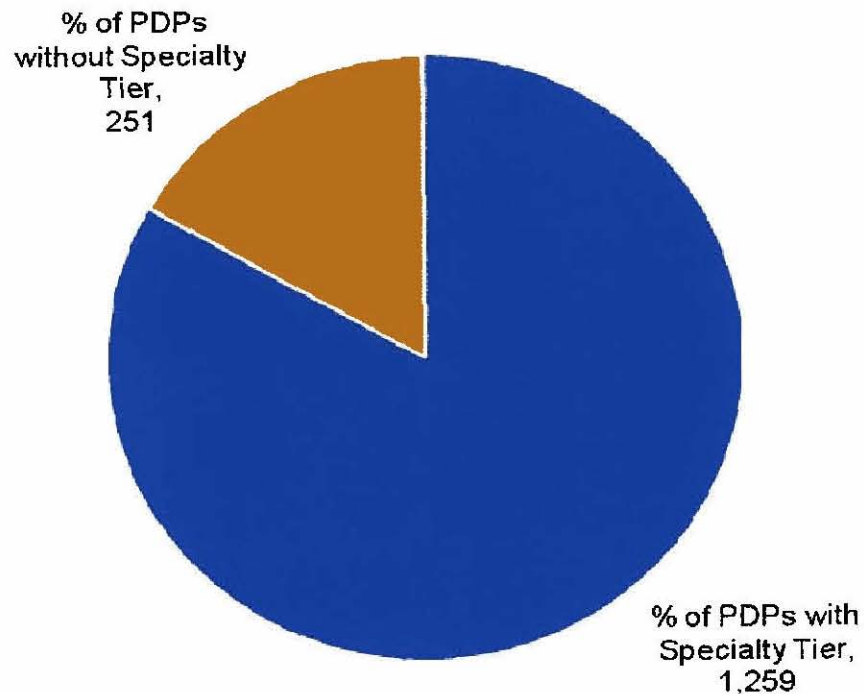
Part D Plans Cover Oral Oncolytics, but Require High Cost Sharing and Prior Authorization

Summary of Part D Coverage of Oral Oncolytics, 2009

Cancer Type	Drug Name	% of Plans: Formulary Coverage	Primary Tier Placement	% of Plans: Prior Authorization	% of Plans: Quantity Limits	% of Plans: Step Therapy	Primary Cost-Sharing Range
Leukemia/ Myeloma	Gleevec	100%	4	70%	29%	0%	25% - 35%
	Revlimid	100%	4	77%	30%	0%	25% - 35%
	Tasigna	100%	4	61%	37%	15%	25% - 35%
Breast	Tykerb	100%	4	74%	42%	0%	25% - 35%
	tamoxifen citrate	100%	1	0%	2%	0%	$ 0 - $10
Kidney	Nexavar	100%	4	61%	34%	0%	25% - 35%
	Sutent	100%	4	62%	32%	0%	25% - 35%
Lung	Tarceva	100%	4	62%	32%	0%	25% - 35%

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. Data from November 2008, reflecting 2009 plan offerings. Avalere analyzed 11 drugs: Gleevec, Hycamtin, Nexavar, Revlimid, Sutent, tamoxifen citrate, Tarceva, Tasigna, Temodar, Tykerb, Xeloda.

Over 80 Percent of PDPs Have a Specialty Tier in 2010



Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2010 data from November 2009.

ASTOUNDING STATISTICS

- Approximately 9% of oral oncolytic claims were reversed
- Approximately 21% of oral oncolytic claims were rejected
- Breast cancer was the top diagnosis code for all rejected claims
- 25% of patients had no apparent follow-up after reversal of their original prescription of an oral oncolytic.

A PICTURE IS WORTH A THOUSAND WORDS……

- The cancer care crisis in this country is so serious that many have joined together as one voice to gain the attention of the members of the House and Senate in the United States Congress.
- Education, Awareness and Data are the keys to success.

Oral Agents in Cancer:

Their Impact on the Treatment of Patients & Providers

American Society of Clinical Oncology

Amended Language Needed House Bill No. 1865

- A patient's out of pocket costs related to coverage for orally administered chemotherapy shall be on a basis no less favorable than coverage provided for intravenously administered or injected chemotherapy.
- A health insurer cannot achieve compliance with this section by imposing an increase in patient out of pocket costs with respect to intravenously administered or injected chemotherapy agents covered under the policy on the effective date of this act

Parity for Pennsylvania