cost and/or insufficient clinical advantage over other therapies. Interviewed EU payers found slow and robust demand for existing agents for favorable health technology assessment (HTA) of personalized therapies, and increasingly seek cost-sharing schemes. However, most surveyed US and EU oncologists preferentially prescribe biomarker-driven agents where appropriate (e.g. 80% of surveyed US oncologists most frequently use pembrolizumab in patients with PD-L1 positive tumors). Furthermore, despite prior authorization and reauthorization being commonly required in the US, and country-specific cost-containment measures (e.g. physician budgets in Germany), the shift in treatment habits most frequently observed in US payers and EU oncologists was the increased use of key prescribing hurdles in the EU. CONCLUSIONS: Strong, demonstrable advantages over existing agents and pricing compromises are required to secure favorable reimbursement for biomarker-driven treatment. While prescribers favor personalized medicine, payers require proven value for money. Manufacturers must strive to help convince payers to see beyond the price tag, and be prepared to balance price expectations with uptake potential to optimize market access.

PCN136 CHARACTERIZATION OF TEMOZOLOMIDE UTILIZATION IN GLOBLASTOMA

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OBJECTIVES: To characterize the usage of Temozolomide (TMZ) in a real-world setting among patients with glioblastoma. METHODS: Adult patients diagnosed with malignant brain cancer (ICD-O-3, CM, 191.X), who underwent brain-surgery related treatment 90 days prior to the first TMZ dose and had ≥ 24 months of continuous enrollment, were identified in the IMS Pharnomics Lifelink Plus claims database. The TMZ + radiation subgroup was used to reflect glioblastoma patients and differentiate them from patients with lower-grade gliomas. Descriptive statistics were generated for patient demographics, insurance-related variables, co-diagnoses, concomitant medications, chemotherapy cycle-duration, and TMZ dose. The index date was defined as the first dose for TMZ, and dates were assessed for pre- and post-index periods. Statistical comparisons between pre- and post-index were performed using McNemar’s tests. RESULTS: A total of 1,126 patients met the inclusion criteria. Mean age of the patients agreed with the standard (p > 0.01). Most patients were tested for BRAF gene mutation testing. BRAF testing appears to be more prevalent in academic centers than in community hospitals. In tumor mass and side effects of the TMZ treatment, a decrease in the use of concomitant medications (anti-inflammatory, antidepressants, and antiepileptic) as well as co-diagnoses (depression, fatigue, seizure/epilepsy, and hear- ing loss) in the post-index period (p < 0.001). However, in this same period, corticosteroid use significantly increased as did the co-diagnoses of aphasia and headache (p < 0.001). TMZ mean starting dose, duration, and number of maintenance phase cycles was 154.4 mg (SD = 77.9), 46 days (SD = 12), and 7 cycles (SD = 3), respectively. Following the first dose, 73% of patients experienced a TMZ dose reduction. CONCLUSIONS: Post-index, patients experienced a complex change in both concomitant medications and co-diagnoses, possibly reflecting both a decrease in tumor mass and side effects of the TMZ + radiation therapy. These initial findings warrant further investigation of TMZ as real-world standard-of-care in glioblastoma.

PCN137 METASTATIC MELANOMA PATIENT CHARACTERISTICS AS A DETERMINING FACTOR FOR BRAF GENE MUTATION TESTING AND TREATMENT IN CANADA – A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: To characterize patients and treatment patterns related to BRAF gene mutation testing. METHODS: An analysis of patient characteristics, diagnostic and treatment planning including BRAF testing, age, morbidity, number of tumor sites, hospital vocation and type of therapy used was conducted using the information included in the IMS BroganEnhanced Tumor Study database from October 2013 to September 2015. RESULTS: Out of 343 stage IV patients evaluated for BRAF mutation, 57% (196 pts.) were BRAF positive, 36% (87 pts.) BRAF negative and for 7% (16 pts.) results were not reported. Patients who were tested for BRAF tended to be less than 50 years of age (46% vs. 16%, p < 0.001), have non or only 1 co-morbidity (87% vs. 62%), have only 1 metastasis (54% vs. 45%, p < 0.05), and treated in an academic facility (74% vs. 50%, p < 0.01) compared to those who were not tested. BRAF negative patients were more often treated with ipilimumab compared to those who were not tested (42% vs. 10%, p < 0.01). CONCLUSIONS: Patients characteristics emerged as an important factor for determining diagnostic and treatment protocols for metastatic melanoma patients in Canada. Younger patients and those with more severe disease characteristics are more likely to be tested for BRAF mutations and treated with ipilimumab in those without BRAF mutation. BRAF testing appears to be more prevalent in academic centers than in community hospitals.

PCN138 BURDEN OF SYSTEMIC LIGHT-CHAIN (AL) AMYLOIDOSIS: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To conduct a systematic literature review on relapsed or refractory AL amyloidosis, focusing on clinical outcomes, epidemiology, health-related quality-of-life (HRQoL) and economic aspects. METHODS: MEDLINE and EMBASE databases were searched for English-language articles published in the last 10 years using search terms including “Primary/Systemic amyloidosis”, “epidemiology/prevalence/incidence”, “therapeutics/drug therapy/outcome”, “patient-reported/quality-of-life/satisfaction/health economic outcomes/cost/etc.”. Search results were manually reviewed, and relevant studies were selected for inclusion as appropriate. Additional refer- ences were obtained from clinical conferences and the reference lists of selected articles. RESULTS: 1,141 articles were initially reviewed, and 58 included in the current review. Given the rare nature of the disease, it was difficult to obtain accurate incidence and prevalence data, but incidence estimates were found to be 0.1-3 per million/year in US. AL amyloidosis is associated with early mortality (median survival <3 years in many series) and a 42-64% rate of non-response or progression. Costly complications of AL amyloidosis include disease-related organ failure. For example, kidney involvement is present in about 70% of patients, and rates of dialysis among US patients with AL amyloidosis range from 7% to 18%. Overall, limbic failure and significant neurologic toxicity are the major concerns with current ther- apies. CONCLUSIONS: Limited epidemiologic and health outcomes data exist in the literature for relapsed or refractory AL amyloidosis. Treatment options are insufﬁ- cient. New therapies which can better clinical outcomes with less toxicity are needed to improve patient care.

PCN139 THE IMPACT OF ENDOSCOPIC LINEAR STAPLING DEVICE STABILITY IN THORACIC SURGERY: A DELPHI PANEL APPROACH

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OBJECTIVES: To develop consensus statements outlining the impact of endoscopic linear stapling device stability on potential complications of thoracic surgery and the antireflection of thoracic surgeons. METHODS: An 8-member expert panel of practicing thoracic surgeons representing eight different countries participated in a Delphi panel process that included two anonymous surveys. The first survey included Likert and Likert-type scale type questions, which were then converted into affirmative statements for the second survey if an adequate number of respondents answered similarly. Consensus was defined a priori when ≥ 70% of respondents agreed on an affirmative statement. RESULTS: All 8 panels (100%) completed surveys 1 and 2. Panelists unanimously agreed an endoscopic linear stapling device with improved stability would result in less stress/ concern for critical firings, surgeries where a fellow is being trained, and robot- assisted surgeries requiring an assistant. Across all tissue types, all panelists agreed that reduced unintentional tissue/structure damage and reduced tension on tissue being fired upon may result from use of an endoscopic linear stapling device that provides improved stability. Stability of These endoscopic linear stapling device stability to have more clinical importance in VATS thoracic surgery compared to open thoracic surgery. CONCLUSIONS: Improved endoscopic linear stapling device stability is a critical component of thoracic surgery that is likely to result in more frequent positive surgical outcomes when compared to a device with greater instability.

PCN140 THE EXPECTED IMPACT OF ONCOLOGY BIOSIMILARS IN BRAZIL AND MEXICO: Payers and Oncologists Consider the Cost-Effectiveness of These CHEAPER ALTERNATIVES

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OBJECTIVES: Brazil and Mexico present an attractive opportunity for biosimilar success due to the large number of patients in these key Latin American markets who rely entirely on government-sponsored healthcare. These public healthcare systems continually strive to limit any premium costs in favor of increasing their suboptimal coverage, particularly of biologics for oncology. This study explores the expected impact of the more cost-effective biosimilar alternatives in Brazil and Mexico on key oncology indications in Brazil and Mexico. METHODS: ACROSS Brazil and Mexico, 100 medical oncologists and 60 hematologists were surveyed regarding their views on biosimilars for breast cancer, colorectal cancer, and Non-Hodgkin’s lymphoma, and on current and expected biologics prescribing patterns. Additionally, 8 payers who influence reimbursement at a national or regional/institutional level were inter- viewed. RESULTS: Up to 41% of biologics-eligible public patients with a given tumor type do not currently receive a biologic, according to surveyed physicians in Brazil and Mexico. Respondents largely attributed low access to limited coverage for oncology biologics. Surveyed physicians and interviewed payers anticipated improved access to biologics upon biosimilar launch and an overall reduced burden from oncology biologics to the healthcare systems. Although surveyed specialists indicate some initial caution regarding the bioequivalence of biosimilars, they nevertheless foresee a widespread biosimilar uptake. In Brazil’s public payers, respondents expect that 70% of Herceptin-eligible breast cancer patients will receive biosimilars—trastuzumab. CONCLUSIONS: Oncology biosimilars should find fertile terrain in Brazil and Mexico. Automatic substitution in the public sector is likely, although interchangeability regulations are currently under discussion in both markets. Cost-effectiveness combined with pharmacovigilance and robust long-term safety data will play a major role in the continuous uptake of biosimilars versus brands, with the latter securing reasonable market share only if priced competitively.

PCN141 PROMOTING MARKET ACCESS THROUGH BREAKTHROUGH THERAPY DESIGNATION: CAN THIS ACCOMPLISH HELP CONVINCE PAYERS AND PRESCRIBERS?

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OBJECTIVES: The breakthrough therapy designation (BTD) pathway aims to expedite approval of drugs for serious and life-threatening conditions. BTD has been awarded to numerous oncology agents in development. This study assessed the likely impact of BTD on payer and prescriber perceptions of novel therapies, and its potential to...
OBJECTIVES: To be considered for funding at a provincial level, all oncolog-
ics must first be appraised at a national level by the pan-Canadian Oncology Drug
Review (pCODR), except in Quebec. This research aims to explore whether there are
any differences between the speed of provincial oncologic access and whether
this varies by provincial wealth and/or population. METHODS: All publically avail-
able provincial funding summaries were extracted from the pan-Canadian Oncology
Drug Review (pCODR), except in Quebec. Quebec oncologic access was assessed
using one-way ANOVA and Student’s t-tests. RESULTS: The average delay between
pCODR recommendations and provincial funding decisions was 8.9 months, which
significantly varied by province (p<0.0001), with the lowest being British Columbia
0.8 months (95% CI 0.1-1.5 months) and the highest being Prince Edward Island (15.1 months). The provinces with populations lower than 1 million experience significantly greater delays to access versus the 5 provinces whose population exceeded 1 million (12.4 vs. 6.1 months). The 4 provinces exceeding 1 million experienced significantly faster time to access than the 5 provinces whose GDP is lower than this (5.1 vs. 12.0 months, p<0.005). However, this relationship does not reach signif-
ificance when GDP is examined on a per capita basis (top 4 provinces: 7.2 months vs.
4.0 months for the bottom 5, p=0.11). CONCLUSIONS: There are significant
variations in time to access for oncology drugs between different provinces. This is
significantly related to the province population and overall wealth but not wealth on
a per person basis. Further research can define whether this reflects differences in
provincial assessments or whether pharmaceutical companies are prioritizing
larger provinces where better market returns can potentially be realised.

PCN145

COMPARING THE VALUE OF A PCODR FULL APPROVAL VERSUS AN APPROVAL CONDITIONAL ON COST-EFFECTIVENESS BEING IMPROVED TO AN ADEQUATE LEVEL

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OBJECTIVES: The pan-Canadian Oncology Drug Review (pCODR) makes recom-
mandations at a national level for oncology drugs. Drugs can only move to provincial
consideration if they receive a pCODR “recommendation” or “recommendation condi-
tional on cost-effectiveness being improved to an acceptable level”. This research aims to
explore how pCODR recommendations affect the time delay to provincial access.
METHODS: All publically available pCODR appraisal reports and provincial funding summaries up to 31 September 2014 were identified from which the appraisal outcomes, incre-
mental cost-effectiveness ratios (ICERs) and dates were extracted. If more than 1
ICER was stated, the mean value was used. Statistical comparisons were performed
using Student’s t-tests. RESULTS: pCODR submissions encompassing 34 indica-
tions were approved in 12/34 submissions. 2/3 were pCODR-recommended, 11/13 recommended conditional on cost-effectiveness being improved to an acceptable level, and 0/13 rejected. There was no significant difference between average delay in provincial access for the submissions that received a full recommendation versus those that received a conditional recom-
mandation (9.3 vs 9.3 months, p=0.49). However, the 7 drugs with an ICER above CAD200,000 per Quality-Adjusted Life Year (QALY) experienced significantly longer delays in provincial access than the 4 drugs whose ICER was below this level (12.3 vs.
8.4 months, p=0.02). CONCLUSIONS: Oncology drugs that are deemed to have
acceptable cost-effectiveness by pCODR did not seem to attain faster provincial access, but this analysis was limited by the small number of pCODR recom-
recommendations with publically available ICERs. Nevertheless, oncologics with higher ICERs experienced significantly greater delays to provincial access. This sug-
ggests that by making greater efforts to demonstrate cost-effectiveness at the level of
pCODR, faster provincial and patent access can be obtained.

PCN146

REIMBURSEMENT APPROVAL OF ONCOLOGY DRUGS IN CANADA SUPPORTED BY A DATA PACKAGE LACKING PHASE III TRIAL DATA

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OBJECTIVES: The Food and Drug Administration (FDA) have approved 28 onco-
logics across 37 indications on the basis of a clinical trial package lacking com-
parative Phase III data (Macaulay, ISPOR Toronto 2014). Approval was typically
granted for indications with no therapeutic alternative where a response rate
>10% was demonstrated. This research aims to define the circumstances under
which oncologics can obtain both regulatory approval and public reimbursement in
Canada on this basis. METHODS: All pan-Canadian Oncology Drug (pCODR) final recommenda-
cions and Provincial Funding Summaries were analysed up to 26th November 2014 and the supportive trial package and key rationale were extracted. RESULTS: 36 submissions were extracted. 4 were pCODR-appraised on the basis of single-arm Phase II trial data. 3/4 were recommended (brentuximab vedotin [Hodgkin’s lymphoma and systemic anaplastic large cell lymphoma] and vismodegib) with pCODR deeming randomized controlled trials (RCTs) to be not feasible. 3 were approved by provinces without any additional restrictions. 18 were also subject to additional restrictions to the approved label. Nevertheless, the incremental cost-effectiveness ratios (ICERs) generated on such data packages were all below the recommended value of CAD200,000 per QALY, as per pCODR’s recom-
mandations on cost-effectiveness being improved to an acceptable level. Nevertheless, within 12 months of all these recommendations, provincial approval was attained in 35
provinces including the largest 3 (Ontario, Alberta, and British Columbia). For the rejected submission (cristizitinib), the ICER was deemed too high and pCODR would not make a recommendation in the absence of comparative survival and quality of life benefits. A subsequent resubmission including Phase III data was recom-
mended. CONCLUSIONS: pCODR will recommend oncologics based on single-arm
Phase II data for indications where RCTs are not deemed feasible but discounting

promote market access leverage. METHODS: Across the United States, 100 medical
and pharmacy directors, 120 oncologists, and 25 managed care pharmacy
and medical directors completed online quantitative surveys to capture their views on
BDT. RESULTS: Surveyed payers were unanimous that BTD will influence formu-
lary decisions for oncology drugs; some 40% said BTD would result in more favorable
tier placement, while 37% expect fewer prescribing controls. However, none of our
surveyed payers considered themselves yet very familiar with the BTD pathway. In
contrast, one third of surveyed oncologists declared themselves to be very familiar with
how BTD works and a total of 88% of oncologists stated the BTD prescribing
formulations, almost 50% agreed that an agent with accelerated approval based on Phase II
data and BTD would more likely be prescribed than such an agent without BTD. Notably,
while BTD includes no guarantee of access to other regulatory pathways other than
fast track designation, surveyed oncologists and payers often perceived BTD approval
and priority review with BTD. CONCLUSIONS: BTD instils confidence in
payers and prescribers, such that this accolade looks set to positively influence reim-
bursement conditions for BD agents, create a buzz, and promote market access for a given agent.
Moreover, associating BTD with accelerated approval and priority review likely further
inspires positivity towards BTD agents. However, that payer respondents are at least
somewhat unfamiliar with the BTD pathway must be considered. Manufacturers who
BDT may significantly reduce their time to market for BTD agents must formulate their market access strategy early and efficiently, and those somewhat unfamiliar with the BTD pathway must be considered. The Food and Drug Administration (FDA) have approved 28 onco-
logics since 2006, 16% in 2008, 17% in 2009 and 14% in 2010) as compared with urban
location (10% from 2006-2008, 12% in 2009 and 11% in 2010). Primary care physicians
and medical professionals were more likely to prescribe opioids (10% in 2006, 12% in 2007,
16% in 2008, 17% in 2009 and 14% in 2010) as compared with surgeons (6%, 11%,
10% in 2006 to 12% in 2010. There was an increasing trend in rural opioid prescribing
factors influencing opioid prescribing and to determine whether rural residency impacts opioid prescribing patterns. METHODS: We used the National
Ambulatory Medical Care Survey (NAMCS) data available for the years 2006-2010. The NAMCS is a representative sample of the utilization of outpatient medical care services in the US. Main outcome measure was opioid drug prescribed. Survey weighted logistic regression models were fit to determine factors influencing opioid prescribing. RESULTS: Opioid prescriptions increased from 10% in 2006 to 12% in 2007 and 14% in 2010 compared with urban
location (10% from 2006-2008, 12% in 2009 and 11% in 2010). Primary care physicians
and medical professionals were more likely to prescribe opioids (10% in 2006, 12% in 2007,
16% in 2008, 17% in 2009 and 14% in 2010) as compared with surgeons (6%, 11%,
10% in 2006 to 12% in 2010. There was an increasing trend in rural opioid prescribing
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