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Subject: BREAKING NEWS: J-codes, 340B Update, RACs, and More...05-16-2019
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BB

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Issue: #4, Volume 29 May 7

Dear Jose Luis,

Hope you are having a fun and productive Spring. **In this issue, we follow u on many topics that we reviewed in previous issues**. First, it's really offic **As we told you in our last issue, J-codes will be issued on a QUARTERI basis**. Wow!! Also, there are a few more improvements that will impact can drugs that we will outline in the first article. All of this innovation news benefi cancer patients and their ability to access novel technologies and drug therap

Additionally, we provide the latest news on 340B. **Once again, the courts upheld the fact that CMS somewhat overstepped their authority and tha 2018-2019 hospital outpatient drug reimbursement rates for 340B drugs therefore not legitimate**. The problem both parties--CMS and hospitals-- ar facing now is what to do about it. Read the article for more info on what's goi on in this long-term fight.

And, look what's coming down the pike. **CMS released statement about ho the RACs will become a kinder, gentler group**. We shall see if this really happens. Also, see our article for some of the topics that RAs can audit, just refresher.

Also, the inpatient PROPOSED regulations were released. This always ramifications for all of us in that the new ICD-10-CM codes are introduc with these regs. Only a few of these new codes impact Oncology this y But, we have them for you along with an overview of the inpatient rules.

And, at long last, Sound Bytes are back for your reading pleasure.

May your May be wonderful,

Da' Mistress

It's Official: Quarterly J-codes!!

At a recent speech, CMS Administrator, Seema Verma, stated that the agency **wishes to expedite the way that innovative new technologies are paid for. This includes several different compone**nts. The first CMS update would revamp the application process for codes under the Healthcare Common Procedure Coding System, or HCPCS.

In the past, the CMS only allowed vendors to apply for new

In the past, the CMS only allowed vendors to apply for new Level II codes once per year. **Now, CMS will redesign the process as a quarterly system for submissions and decisions related to drugs** and a semi-annual system for submissions and decisions related to devices. **The interesting part of this strategy is that they are starting it right away! Ju dates of service forward will see the advent of the following codes:**

HCPCS/MOD Code	Action	Short Descriptor	Long Descriptor
Q5112	add	Inj ontruzant 10 mg	Injection, trastuzumal dttb, biosimilar, (Ontruzant), 10 mg
J9355	revise	Inj trastuzumab excl biosimi	Injection, trastuzumal excludes biosimilar, 1 mg
Q5113	add	Inj herzuma 10 mg	Injection, trastuzumal pkrb, biosimilar, (Herzuma), 10 mg
J7208	add	Inj. jivi 1 iu	Injection, factor viii, (antihemophilic factor recombinant), pegylat aucl, (jivi), 1 i.u.
Q5114	add	Inj ogivri 10 mg	Injection, Trastuzuma dkst, biosimilar, (Ogiv 10 mg
J7677	add	Revefenacin inh non-com 1mcg	Revefenacin inhalatio solution, fda-approve final product, non-compounded, administered through DME, 1 microgram
Q5115	add	Inj truxima 10 mg	Injection, rituximab-al biosimilar, (Truxima), mg
J9036	add	Inj. belrapzo/bendamustine	Injection, bendamusti hydrochloride, (Belrapzo/bendamust 1 mg
J1444	add	Fe pyro cit pow 0.1 mg iron	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron
J9030	add	Bcg live intravesical 1mg	BCG live intravesical instillation, 1 mg
J9031	d/c		
J9356	add	Inj. herceptin hylecta, 10mg	Injection, trastuzumal 10 mg and Hyaluronidase-oysk

The second component outlines **coverage of Current Procedural Terminol or CPT, temporary codes for emerging technologies, also known as category III codes**. For technologies that don't fall under an existing local coverage determination, Verma said Medicare contractors are not authorized automatically forgo covering category III items and services. Instead, these contractors must follow the agency's new local coverage determination proce for each decision they make. That process includes an evidence review of th technology in question.

The other technological advancement is that the **technological add-on to th inpatient discharge-based payment called the DRG will be increased. Th will help expensive drugs, like CAR-Ts, that are only given to inpatients**

our article on the PROPOSED Inpatient Rule for more details.

Any questions? E-mail me...

Update: The 340B Payment Impasse

U.S. District Court Judge Rudolph Contreras again ruled last week that 340B drug reimbursement rate that Health and Human Services set in tl 2019 Outpatient Prospective Payment System (OPPS) rule is unlawful, a decision that earned praise from various industry stakeholders.

This ruling comes five months after the Court first ruled against the 28.5% cu December to 340B hospital outpatient drug payments that HHS Secretary Al Azar instituted in Calendar Year 2018. **Contreras stated that the cuts were implemented "in contravention of the Medicare Act's plain text."** Medica Part B reimburses prescription drugs to hospitals participating in the program the average selling price plus 6%, well above the average selling price minus 22.5% as HHS had proposed in 2018 strictly for 340B hospitals.

"The Court also concludes that, despite the fatal flaw in the agency's rate adjustments, vacating HHS' 2018 and 2019 rules is not the best course of ac given the havoc that backtracking on these payments may wreck on Medicar administration," Contreras wrote in the 22-page ruling.

What that means is that U.S. District Judge Rudolph Contreras did not g hospitals the permanent injunction against the cuts that they wanted. A he did not cancel all rates retroactively. Instead, the Judge ordered the department to take "first crack" at a remedial measure with a status update b August 5, 2019. HHS will have "first crack" at crafting appropriate remedies f the two rules, 2018 and 2019, according to the ruling.

Kinder, Gentler RACs???

The Medicare Fee-For-Service (FFS) Recovery Audit Contractor (RAC) Prog is one of retrospective devices CMS uses to prevent and reduce improper payments. Per their scope of work, RACs identify and correct overpayments made on claims for health care services provided to beneficiaries, identify underpayments, and provide information that allows CMS to recoup money a prevent future improper payments. That's the party line. Providers, particular hospitals, have long complained about the administrative burden posed by th RACs.

CMS is claiming that they have reduced RAC-related provider burden to all-time low, as evidenced by the significant decrease in the number of RAC-reviewed claim determinations that are appealed and the corresponding reduction in the appeals backlog.

Some experts believe that this blog post claiming to decrease the administra burden is a false flag. The RACs did not receive new contracts or revised sc of work. So, these experts are unsure where exactly this change is coming f or whether it is real or positive for providers.

Examples of key improvements and enhancements, according to CMS in the post:

- Better oversight
- Holding RACs accountable for performance by requiring them to main a 95% accuracy score
- Requiring RACs to maintain an overturn rate of less than 10%
- RACs will not receive a contingency fee until after the second level of appeal is exhausted
- Reducing provider burden and appeals
- Making RAC audits more fair to providers
- Changing how we identify who to audit
- Giving providers more time to submit additional documentation before

- Giving providers more time to submit additional documentation before needing to repay a claim
- Increasing program transparency
- Regularly seeking public comment on newly proposed RAC areas for review, before the reviews begin
- Requiring RACs to enhance their provider portals to make it easier to understand the status of claims

Just as a reminder to Oncology practices and clinics, here are some of topics, which might impact cancer, that the RACs are currently allowed audit:

- Not a New Patient (Must be 36 months since anyone in the practices l seen the patient)
- HERCEPTIN® unit billing when using the multidose vial
- Discharge Day services (Only one may be billed by one provider)
- Add-on codes without a primary procedure
- Excessive drug units billed (Most popular)
- Provider services during hospice
- "Initial" hydration billed (Only one initial code per day, must be over 30 minutes)--Hospital outpatient only
- Exact duplicate claims

For more information visit the Medicare FFS Recovery Audit Program websit
See the full text of this excerpted CMS Blog (issued May 2).

PROPOSED Medicare Inpatient Rule & ICD-10-CM for 2020

The Centers for Medicare & Medicaid Services in the last week of April issued a proposed rule that would increase Medicare inpatient prospec payment system rates by a net 3.2 percent in Federal Fiscal Year 2020, compared to FY 2019, for hospitals that are meaningful users of electronic health records and submit quality measure data. Additionally, the rule makes changes to:

- Disproportionate Share Hospital payments: For FY 2020, the agency estimates that it will distribute $8.49 billion in DSH payments, an incre of approximately $216 million compared to FY 2019. In addition, **CMS proposes to use a SINGLE year** of uncompensated care data to determine the distribution of DSH uncompensated care payments for 2020. Previously, CMS had averaged three years of data.
- Tech Add-ons to DRGs: CMS also proposes to increase the marginal of the new technology add-on payment, including for CAR-T therapies from 50 to 65 percent.
- CAR-Ts: CMS has not proposed to modify the current MS-DRG assignment for cases reporting CAR T-cell therapies for FY 2020. Inst CMS plans to continue New Technology Add-on Payments (NTAPs) fo CAR T-cell therapies for FY 2020, proposing to increase NTAPs from of estimated costs of the case to 65%. Raising the NTAP percentage would increase the maximum add-on payment from $186,500 to $242 Moreover, CMS has solicited comments on other payment alternatives FY 2020 CAR T-cell therapy, and whether cases assigned to any pote new MS-DRG for CAR T-cell therapy should exclude indirect medical education and DSH payments, which are DRG adjustments for qualify hospitals.
- Wage Index Changes: CMS proposes changes to the area wage inde which inflates DRGs for differences in wages between areas. Among proposals, the rule would increase the wage index for hospitals with a wage index value below the 25th percentile. This is particularly for rur hospitals. It also would decrease the wage index for hospitals with val above the 75th percentile to make this policy budget neutral.
- Quality Overview: CMS further proposes a number of updates to its hospital quality incentive programs. It would add three new electronic clinical quality measures to the inpatient quality reporting program

clinical quality measures to the inpatient quality reporting program including two opioid-related measures and a hybrid hospital-wide all-c readmission measure.

In addition, attached to the PROPOSED Rule are Tables which provide chan to the ICD-10-CM system starting at the beginning of the Federal Fiscal Yea which is October 1, 2019. Tables 6A-6J show changes to the ICD-10-CM system. **Here are some possible codes for cancer clinics and practices year. PLEASE review all of the new codes, if you code inpatient charts are multi-specialty in your facility**:

Diagnosis Code	***Description***
D75.A	Glucose-6-phosphate dehydrogenase (G6PD) deficiency without anemia
D81.30	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
T50.911A	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), initial encounter
T50.911D	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), subsequer encounter
T50.911S	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), sequela
T50.912A	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, initial encounte
T50.912D	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, subsequent encounter
T50.912S	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, sequela
T50.913A	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, initial encounter
T50.913D	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, subsequent encounter
T50.913S	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, sequela
T50.914A	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, initial encounter
T50.914D	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, subsequent encounte
T50.914S	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, sequela
T50.915A	Adverse effect of multiple unspecified drugs, medicaments a biological substances, initial encounter
T50.915D	Adverse effect of multiple unspecified drugs, medicaments a biological substances, subsequent encounter
T50.915S	Adverse effect of multiple unspecified drugs, medicaments a biological substances, sequela
T50.916A	Underdosing of multiple unspecified drugs, medicaments ar biological substances, initial encounter
T50.916D	Underdosing of multiple unspecified drugs, medicaments ar biological substances, subsequent encounter

T50.916S	Underdosing of multiple unspecified drugs, medicaments ar biological substances, sequela
Z71.84	Encounter for health counseling related to travel
Z86.002	Personal history of in-situ neoplasm of other and unspecifie genital organs
Z86.003	Personal history of in-situ neoplasm of oral cavity, esophagu and stomach
Z86.004	Personal history of in-situ neoplasm of other and unspecifie digestive organs
Z86.005	Personal history of in-situ neoplasm of middle ear and respiratory system
Z86.006	Personal history of melanoma in-situ
Z86.007	Personal history of in-situ neoplasm of skin

CMS will accept comments on the proposed rule through June 24, 2019
These rules go into effect October 1, 2019.

SOUND BYTES

340B drug reductions is not the only problem hospitals have faced over the past few years from Medicare. Site neutral payments have reduced payments to hospitals from non-grandfathered Provider-based facilities . Two U.S. House of Representatives lawmakers recently launched a bipartisan effort to override the Trump administration's site-neutral pay regulation.
Representative Derek Kilmer (D-Wash.) and Rep. Elise Stefanik (R-N.Y.) want to block a final CMS rule that went into effect January and cuts Medicare rates for hospital off-site clinics for some outpatient treatments. Their bill is backed by the American Hospital Association and the Federation of American Hospitals, which represents investor-owned systems and they are looking for senators to introduce companion legislation in that chamber...**Ever feel that hospitals get paid more than practices? Modern Healthcare reports that p rivate employer-sponsored health plans paid hospitals 241% of Medicare prices, on average, for the same services a same hospitals in 2017, according to a RAND Health study of prices acr 25 states.**
That average price relative to Medicare has increased since 2015 when it wa 236%. The study also found that relative prices in 2017 for outpatient care fa exceeded prices for inpatient services...Drugmakers will now have to post pri on their ads. This oughta be interesting!!! **Health and Human Services Secretary Alex Azar announced a final rule from the Centers for Medica Medicaid Services (CMS) that will require direct-to-consumer television advertisements for prescription pharmaceuticals covered by Medicare Medicaid to include the list price - the Wholesale Acquisition Cost** - if th price is equal to or greater than $35 for a month's supply or the usual course therapy. If a manufacturer simply includes price information in a direct-to-consumer advertisement as required by § 403.1202, that information in the advertisement will not require review by the FDA Office of Prescription Drug Promotion (ODPD)...**As you may know, the Department of Justice is tryir overturn the Affordable Care Act in the courts.** Assuming that the ACA survives,
Insurers are projected to submit rate increases in the Affordable Care Act market of about 10 percent, which is higher than the roughly 6 perc increase for 2019, according to Dave Dillon,a fellow of the Society of Actuar and senior vice president of Lewis & Ellis, Actuaries and Consultants. An estimated 2 percent of the increase will be due to the return on the health insurance tax. Medical inflation will account for 4-8 percent of the increase, w Dillon called a normal annual trend reflecting the underlying growth in healthc costs...**Think private practice is disappearing?? You'd be right!!** For the f time, employed physicians outnumber self-employed physicians, according t 2018 benchmark survey from the American Medical Association (AMA). The

findings underscore a long-time trend of shifting ownership across physician practices. **Over the last several years, self-employed physicians have be on the decline.** In 2018, nearly half--47.4%--of all patient care physicians we employed physicians, up 6% from 2012. In 2018, 45.9% of all patient care physicians were self-employed, down 7 points since 2012. Seven percent of physicians were independent contractors...Medicare Advantage patients now represent approximate 36% of Medicare beneficiaries. And, guess what, the spend less--but, maybe they were that way before opting into MA. A recent s published Monday turns that claim on its head. Researchers at the Kaiser Fa Foundation found that traditional Medicare beneficiaries who opt to enroll in a Medicare Advantage plan offered by a private health insurer have lower aver spending and use fewer services-before they ever switch to Medicare Advan than their counterparts who stay in traditional Medicare. **The findings raise questions about how much Advantage plans actually lower spending.** Moreover, the results suggest that the CMS, which uses traditiona Medicare spending to calculate Advantage payments, overpays Medicare Advantage plans to the tune of billions of dollars each year, the researchers concluded...**Ever wonder how many diagnoses you should record on a claim?**? You can report up to 12. But, should you? This really cool article gi you some answers.

Remember this newsletter is a summary of regulations for Medical Oncology a preliminary reading of complex coding and billing material. There may be t and misinterpretations. Providers are responsible for the information on evei claim. Payers have differing rules and interpretations thereof. Reading this newsletter does not substitute for understanding regulations and verifying the validity of every claim. This information is time-sensitive and is subject to constant change. onPoint Oncology Incorporated and/or its partners/founder accepts no liability for any statements or articles herein. Statistics given here are valid for the date of report only.

Sincerely,

Da' Mistress of All She Surveys

Sincerely,

Roberta Buell
onPoint Oncology LLC