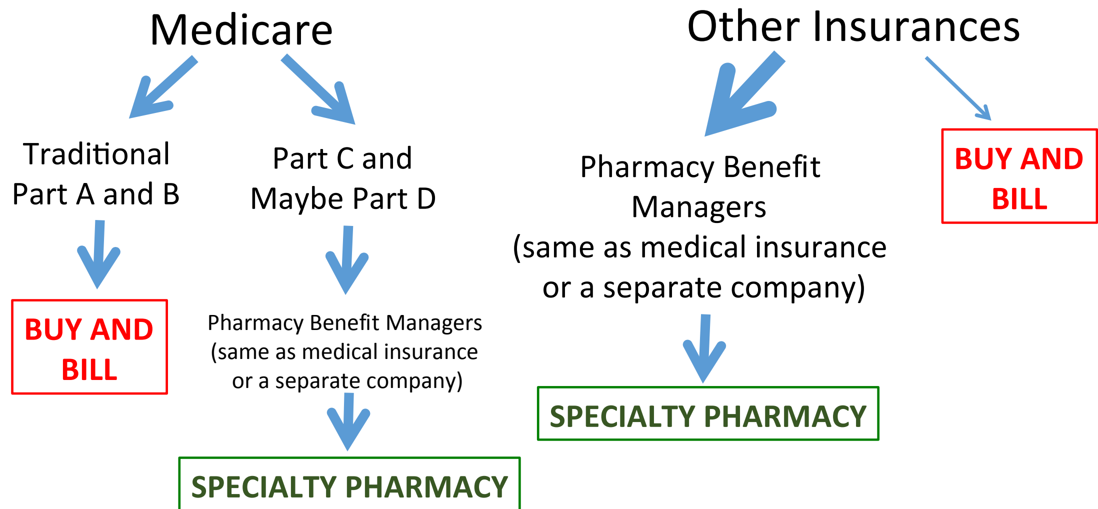
Expanding the Scope of Practice - Biologics

1. Quick Overview of the Pharmacy Insurances in the United States



2. Discussion Disclaimer

- **No one right way to do this**
- **Insurance and state variations and practice sizes vary**
- **We all are learning, including your panelist(s)**

3. Paperwork

- Forms and Clinical Documentation – Needs expertise
  - Prescription forms
  - Collecting all of the supporting data
  - Mistakes can cause rejections
- Tracking
  - Company Gateways – the good ones, the bad ones
  - Help from company representatives
  - Internal tracking within your own practice – tracking spreadsheets
- Insurance Formularies
  - Incorrect knowledge of mechanisms (anti-IgE vs. anti-IL5)
  - Different criteria and restrictions but generally follow phase 3 protocols
- **Rejections**
  - **Keeping track of rejections and why**
  - **Appeal letters – who can help write these and reusing old letters**
  - **Peer-to-peer appeals and within the same specialty**
- **Specialty Pharmacies**
  - **Poor Communication, like hold times on the phones**
    - **Ask for a direct point person or a direct number**
  - **Is it easier to deal with specialty pharmacies directly vs. company gateways?**

- Shipping and Receiving
  - Who calls to have the biologics order to be shipped – We ask the patient.
  - Tracking in the office who receives drug and documenting receipt
  - Communication among pharmacy, patient, and practice
- Administration
  - **Documentation of clinical reason and clinical benefit**
  - Dose, lot numbers, drug waste
  - Correct diagnosis and injection codes
  - Compliance with drug and noncompliant patients
    - How to deal with vials of drug in noncompliant patients
- Continuation of Drug
  - Changes in insurance – Affordable Care Act
  - Patient moving to another practice
  - Renewal restrictions - Renewals every 3-12 months
  - Changes in the process, including forms, insurance formularies and restrictions, and specialty pharmacies
- Patient financial responsibility
  - Deductibles and copays and Tracking Insurance Changes
  - Financial assist programs and foundations
- **Buy and Bill Issues**
  - **Traditional Medicare and some private insurance companies**
  - **Understand Discounts and Rebates**
  - **Inventory of drug**
  - **Documentation and coding of the diagnosis**
  - **Billing correctly the number of UNITS of drug**
  - **WAC - Wholesaler Acquisition Cost - the national acquisition cost is determined by the drug manufacture**
  - **WAC is used by Medicare to establish the initial reimbursement of an unclassified biologic. 06% of the WAC=reimbursement, after the ASP is established the reimbursement changes. This goes hand in hand with the establishment of the CPT code.**
  - **Many commercial plans use the WAC in the formula for establishing your reimbursement**
  - **ASP- Average Selling Price: Calculated quarterly by Medicare using all cost data submitted by the manufacturers. Currently Medicare reimburses most biologics on an ASP + 6%. This can change quarterly (Jan/April/July/Oct).**
  - **Rebates based on volume**

4. **<u>Revenue Cycle Management</u>**
- Financial counseling of patients and your staff
  - Copay and deductibles
  - **Foundation programs – check back vs. credit cards**
  - Insurance changes
- Collection of payment
  - Payment plans
  - **Credit Card on file**
- **Injection Codes: Chemotherapy vs. Regular Injection**
- Requiring office visits with injections
- Double Check Claims Submissions
  - Buy and Bill vs. Specialty Pharmacy – billing of the drug

- Insurance changes
  - Price changes of the drugs and Price changes of the injection
  - New restrictions on its clinical use

5. **Workflow and Staffing**
   - **Total number of patients on biologics**
     - **A threshold number when need to centralize tasks**
     - **Number of physicians in the practice**
   - **Personnel**
     - **Multiple people handling biologics vs. central coordinator**
     - **Educational experience of the personnel – nurse vs. administrator**
   - Training of the personnel
     - Clinical training of the disease – important for appeals
     - Documentation and paperwork
     - Learning and improving the workflow of biologics handling
     - Administration of drug and adverse reactions to the drug
   - Education and consenting of patients
     - Understanding of the specialty pharmacy process
       - It's not as simple as going to a pharmacy
     - Patient responsibility for getting the drug to the office
     - **Consider consent forms**
     - Compliance with the drug
     - Set and manage expectations, like the response to drug, wait times
     - Possible adverse reactions
     - Also educate your practice staff on the process
   - Dealing with shipment and receiving of drugs
     - Inventory of drugs and Storage of drugs
   - Disaster preparation – no electricity, floods, equipment failure
   - **Scheduling of patients**
     - Walk-ins vs. Appointments
     - Set days for administration
   - Policies for drug administration
     - No shows and last minute refusals (omalizumab)
   - **Administering the drug**
     - **Like immunotherapy – specific personnel and physical space**
   - Dealing with Adverse Reactions
     - Anaphylaxis and Epinephrine auto-injectors

Pearls for Biologic Therapy

Correct documentation will help you get the approval done right the first time.

Understand the mechanisms and what is needed for approval for each medication.
Variations exist throughout the country.

- For example, is spirometry with an fev 1<80 required?
- What is the eosinophil count needed for a particular Anti-IL5 agent?
- What is the IgE level for Xolair?

Have a solid medication history listed

- ICS/LABA
- Leukotriene Modifier
- LAMA
- Prednisone use- How much?
- Rescue inhaler use
- ER/Hospitalizations/ICU admissions

With insurance/specialty pharmacy/company contacts-

- Have a direct phone number and a name of a person

Minimize office burden

- Ask patient to help call for the order to be shipped and also take responsibility
- Our patients call 1 hour prior to Biologics to make sure dosage isn’t wasted/prep done
- Have patient call for Assistance Programs.
- 1 Central Coordinator/Other staff involved
- Workflow requirements

Document Clinical Benefit and Use the correct Codes

- If you have a visit- code the reason for the visit separately from injection code

Buy and Bill

- It is not just Buy and Bill for Medicare. Commercial Insurance does buy and bill as well.
- Purchase Agreements vary- have invoice discounts, price protection,
- Volume based discounts
- Wholesaler Acquisition Cost (WAC) -national acquisition cost by the manufacturer
- Average Selling Price (ASP) -Quarterly calculation by Medicare using cost data by manufacturers
- General Medicare reimbursement is ASP + 6%-- BUT Commercial can greatly vary

Anaphylaxis Precautions- Epinephrine Auto Injectors

Office based OIT and OFC
Mohamed Yassin, MD and Douglas Jones, MD

Staff:

1. Train your staff before starting OIT or OFC and periodically retrain especially with new hires. Well educated and trained staff are more likely to recognize symptoms and signs of reactions AND less likely to make dosing errors.
2. Make sure you and your staff are ready to resuscitate when needed.
3. When preparing food(s) for OIT and OFC, double checking in all steps is a must; name, date of birth, food type, source of food, concentration, dosage (develop a checklist).
4. Before each dose inquire about any new symptoms and look for any signs of reactions; double check the dose and patient's name and date of birth
5. Proficiency in OFC is a pre-requisite to OIT. When starting OIT, the number of OFC's you do will greatly increase

Office space:

1. Patient scheduling is an art. Figure out what works for you and your staff, consider scheduling OIT patients in early am slots.
2. For OFC patients consider a well-trained dedicated nurse with the patient at all times.
3. Avoid having OFC patients waiting in the waiting room between doses.
4. OIT patients need to be checked on frequently after up-dosing whether kept in exam rooms, holding areas or the office waiting room.
5. Waiting rooms may not be appropriate if your front staff is not well-trained or preoccupied by attending to a large number of patients and or phone calls.
6. Many offices that do large numbers of OIT are utilizing holding areas (bigger exam rooms) or dedicated open areas where nurses are able to watch patients. These areas hold 4-6 families.

Supplies for OIT and OFC:

1. Appropriate supplies will make it easier for your staff to deliver appropriate care and avoid costly mistakes. (the right form of food, scale, Ziploc bags, bottles,…..).

Billing:
There is no specific CPT code for OIT

1. 95180: Rapid Desensitization procedure, each hour (eg, insulin, penicillin, equine serum). CMS/Medicare: "Desensitization to food allergens is a potentially dangerous procedure and has not been proven effective. Payment for this form of immunotherapy will be denied as not proven effective"
2. 95076: Ingestion Challenge Test (**sequential and incremental** ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing. (>61 min required)
3. 95079: each additional 60 minutes of testing. (>31 minutes required)
4. CMS may limit maximum of 4 hours between the 2 codes (95076/95079) combined
5. 95076/95079 are diagnostic are not therapeutic codes. If you are performing a desensitization, use 95180
6. E&M is included in these codes. Use if justified due to additional evaluation and management (example; treatment of reactions or management of coexisting asthma).

Charge for OIT supplies:

1. Some practices charge each patient $250-300 for supplies when starting OIT. This is not applied to insurance payments.

Useful Tips and Information for Office Administration of IVIg and HAE drugs

- Key point: The majority of practices and not doing this via buy and bill and in fact most practices large and small have transitioned to SQIg given by patient to themselves at home.
    - This may change with new approval for neurologic treatment and partnership with neurologist may be a way to make this work in high enough volume to make it profitable.

- See: http://www.medicarepaymentandreimbursement.com/2011/08/cpt-jcode-j0850-j1459-j1561-j1568-j2788.html for a comprehensive review of CPT codes and proper associated ICD-10 codes that justify proper CPT codes.

- See: http://healix.net/ for an example of a company that partners with physicians to provide infusion services.

- HAE drugs are cost prohibitive from a buy and bill perspective in most cases and administration in office requires correct coding and often the patient to provide the drug for use. Most producers of HAE medication have a free replacement policy if you or your local hospital stocks the drug and it expires prior to use.

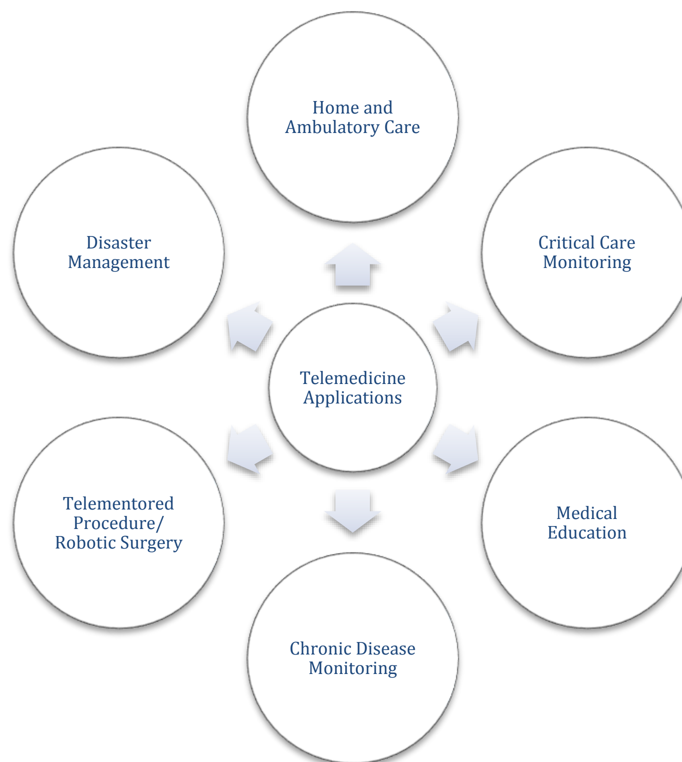
- C9015 is the CPT code. J3590 is appropriate J code. These must be paired with proper ICD-10 codes for HAE by type if known.

General Tips:

- Streamline PA's process as much as possible. Prepopulate forms with office name, provider number, NPI, and general rationale for treatment so that process is rapid and consistent. Develop scripts with nursing staff for phone conversations.
- Ensure you know which plans handle this through PBM vs. Primary Insurer and whenever possible develop a good relationship with a specialty pharmacy and use them whenever possible.
- Anticipate lab work required by insurance for approval and repeat approval so that process is smooth and quick for patients on product already.
- Don't be afraid to use local hospital infusion center if this will make the process easier for you or your patient. Some payers prefer this.
- Take advantage of any and all services provided by pharmaceutical companies or specialty to pharmacies to help you get approval and patients to get co-pay assistance.

AAAAI Practice Management Workshop 2018-Telemedicine Tips:

1. What is telemedicine?
    - Asynchronous
    - Synchronous
2. Is Telemedicine for me?
    - Financials
        - Reimbursement
    - Time commitment
        - Sole practice
        - Incorporate into existing practice
3. How do I get started?
    - Licensure
    - Support
        - Tech
        - Staff
        - Ancillaries
    - Malpractice
    - Documentation
    - Scheduling
4. How do I prepare for the actual visit?
    - Tech
    - Webside manners



Helpful Resources:

Elliott T, Shih J et al. American College of Allergy, Asthma, and Immunology Position Paper on the Use of Telemedicine for Allergists. Ann Allergy Asthma Immunol. 2017;119(6):512-7.

http://www.americantelemed.org/home

https://evisit.com/state-telemedicine-policy/

http://www.idsociety.org/uploadedFiles/IDSA/Manage_Your_Practice/Updates/Modifiers%20Telemedicine.pdf

Position Statements

The taskforce on telemedicine in Allergy supports the following statements:

1) Telemedicine is a method of healthcare delivery that may enhance patient-physician collaborations and compliance, reduce overall medical cost, improve health outcomes, and increase access to care.
2) Telemedicine activities should account for varying literacy and technologic literacy levels and strive for ease of use in interface design, content, and language.
3) The use of telemedicine must be secure and compliant with state and federal regulations.
4) Provider groups should confirm that medical liability coverage includes a provision for telemedicine services.
5) Clinical judgment should be used when determining the scope and extent of telemedicine services provided to patients.
6) Quality assurance measures should be in place to track patient satisfaction, physician performance, and clinical outcomes whether at an originating site or via home based telemedicine care.
7) Live interactive video visits with allergy patients should be at the same standard of care and held to the same standards of professionalism and ethics as in- person consultations.
8) Live interactive video visits should be reimbursed at the same rate as in-person care and there should be transparency and understanding of payor reimbursement for different modes of telemedicine delivery.
9) Best practices for safety in telemedicine care delivery should be followed at all times.
10) Roles, expectations and responsibilities of providers involved in the delivery of Allergy care should be clearly defined.
11) Appropriate technical standards should be upheld throughout the telemedicine care delivery process and specifically meet the standards set forth by the Health Insurance Portability and Accountability Act (HIPPA).
12) Time for data management, quality processes, and other aspects of care delivery related to telemedicine encounters should be accounted for by the provider organization and recognized in value-based care delivery models.
13) Telemedicine utilization for allergy care is likely to expand with broader telehealth applications in medicine; further research into impact and outcomes are needed.
14) A streamlined process for multistate licensure would improve access to specialty care while allowing states to retain individual licensing and regulatory authority.