













ORAL CORTICOSTEROID STEWARDSHIP STATEMENT

November 2018

It is time to protect patients with asthma from potential overexposure to oral corticosteroids (OCS) – and to recognize OCS overuse for what it often is: a treatment plan failure.

OCS carry serious health risks (page 2). Innovative treatment options target certain types of severe or difficult-to-control asthma in ways never-before possible, reducing the need for OCS. Today, OCS use has become a signal that a patient may need an updated treatment plan, or support with adherence concerns. While OCS can be an important tool in managing asthma in certain cases, use should always be carefully monitored by a qualified asthma specialist, or a primary care provider with asthma expertise. **NOTE:** OCS should not be confused with ICS

(inhaled corticosteroids), which have fewer risks (page 2).

Within this context, we, the undersigned, are embarking upon a collaborative, systematic effort to curb OCS overexposure by:

- 1. Educating patients and their caregivers about (1) the risks associated with OCS; (2) the importance of adherence to other asthma medicines; and (3) advanced treatment options.
- Ensuring that patients have access to qualified asthma specialists, or primary care providers with asthma expertise, who can (1) address adherence concerns; (2) determine if a patient has a severe, difficult-to-control form of asthma that might benefit from innovative targeted treatments; and (3) carefully monitor OCS use.
- Supporting healthcare providers (allergists, pulmonologists, and primary care) to develop and adopt OCS-sparing strategies and practice shared decision-making.
- Urging government agencies to modernize public health policies and materials to reflect the importance of OCS-sparing interventions.
- Petitioning payers to adopt OCS-sparing strategies by providing appropriate and timely access to conventional and advanced

PATIENT INSIGHTS⁵

A recent survey of 519 adults with asthma found that:

- Nearly 85% used at least one burst of OCS in the past 12 months.
- 64% had done so two or more times.
- About 20% did not equate >2 bursts of OCS (in a 12-month period) with poor asthma control or asthma severity.
- 78% of those who currently see an asthma specialist had received an OCS Rx from someone other than their specialist.
- 70% of those who currently see an asthma specialist report their doctor has talked to them about the risks/side effects associated with the overuse of OCS.
- Over half of patients surveyed were not aware of other innovative treatments options for severe or hard-to-control asthma.

* Polling conducted by the Asthma and Allergy Foundation of America, June 2018.

- treatment options based on the clinical judgment of the treating HCP in consultation with the patient.
- 6. Ensuring primary and urgent / emergency care providers recognize when to refer patients to an asthma specialist, or a primary care provider with asthma expertise.
- 7. Empowering urgent / emergency care providers, pharmacists, asthma educators, and other health professionals to engage with patients about OCS risks at point-of-care.

ABOUT ASTHMA

Asthma is a chronic lung condition affecting 26.5 million Americans.⁴ Five to ten percent of the total asthma population are believed to have severe asthma.¹

Asthma causes coughing, wheezing, chest tightness, and shortness of breath. ^{1,12} Severe or difficult-to-control asthma can be debilitating to patients, negatively impacting their lives at home and at school or work. ^{5,12} Sudden severe symptoms can be fatal. ¹²

There is no cure for asthma, but a range of conventional and advanced medications can help control symptoms. When conventional medicines do not work despite proper adherence and administration technique, it can be an indicator of a severe or difficult-to-control type of asthma. 1,2,6

INDICATORS OF UNCONTROLLED ASTHMA^{1,6,7,8}

- Requiring more than two courses or bursts of OCS in a 12-month period.
- One or more asthma episodes requiring a call to 911, emergency room visit, or hospitalization in the past 12 months.
- **3.** Use of quick-relief inhaler more than two times per week.
- **4.** Refilling a quick-relief inhaler more than two times a year.
- **5.** Limitations doing everyday activities like exercising or household chores.

OCS Health Risks

Even short-term low-dose use of OCS (under 30 days) can result in serious health problems. One 2017 study* revealed that U.S. patients using OCS short-term doubled their risk for fracture, tripled it for blood clots, and had a fivefold increased risk for sepsis. *study was not solely focused on patients using OCS to manage asthma.

Other OCS Risks include: 3,10,11

Short-term:

- Elevated eye pressure (glaucoma)
- Fluid retention (causing swelling in lower legs)
- High blood pressure
- Problems with mood, memory, and behavior
- Weight gain (abdomen, face, and neck)

Longer-term:

- Cataracts (clouded vision)
- High blood sugar (can trigger or worsen diabetes)
- Infections
- Osteoporosis
- Thin skin, bruising, slower wound healing

INHALED VS. ORAL CORTICOSTEROIDS

Conventional medications often include inhaled corticosteroids, which are not the same as OCS and result in much lower overall steroid exposure than even one course of OCS.

SAMPLE TRANSPARENCY STATEMENT: The following organizations served as thought partners in the assembly of this statement: AstraZeneca, Boehringer Ingelheim, Boston Scientific, GlaxoSmithKline, Novartis, Regeneron, & Sanofi.