



## **JULY 2024**

THE NUMBERS LISTED
BELOW ARE FOR
FEE-FOR-SERVICE (FFS)
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Prime/Magellan Rx
Pharmacy Support Center
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1-800-424-7895
Monday – Friday
8:00 a.m. – 5:00 p.m.,
Central Time (CT)
excluding State holidays

Clinical PA Fax 1-800-424-7976 24 Hours A Day, 7 Days a Week

Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Week

Division of Medical
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Little Rock, AR 72203
Fax: 501-683-4124 OR
800-424-5851
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### DRUG UTILIZATION REVIEW (DUR)/DRUG REVIEW COMMITTEE (DRC) BOARD UPDATE

The following will be presented during the July 17, 2024 DUR/DRC Board meeting.

Preferred Drug List Review	Vaginal hormones and multiple sclerosis agents	
Proposed Point-of-Sale Changes	Fraiche toothpaste	
Policy change	DAW Code review, Bylaws review	
Manual Review PA Criteria	Vitiligo, Pustular Psoriasis, Rezdiffra™, Wegovy®,	
	Tryvio™, Voydeya™, Lymepak™, Myhibbin™, Crysvita®	

https://ar.magellanrx.com/documents/d/arkansas/dur-drc-board-agenda-for-july-17-2024

#### DIABETIC SUPPLIES

As previously communicated, Arkansas Medicaid is updating the billing processes for diabetic supplies including Continuous Glucose Monitors (CGMs), which will be changing to a pharmacy claim type submission by both pharmacies and DME providers. The official start date is 8/1/2024 for both DME providers and pharmacy providers. Registration for the new diabetic supply billing portal opens 7/1/2024 accessed through https://ar.magellanrx.com/home

Mark your calendars for the new portal training sessions for DME providers. The new portal training sessions times for DME providers are below:

- July 2nd 10:00 am Link to Teams meeting
- July 3rd 10:00 am Link to Teams meeting
- July 9th 10:00 am Link to Teams meeting
- July 9th 1:00 pm Link to Teams meeting

Each meeting listed above has an embedded link for that specific meeting. If there any issues or concerns with those links, please email <a href="mailto:cynthia.neuhofel@dhs.arkansas.gov">cynthia.neuhofel@dhs.arkansas.gov</a> to get a calendar invite forwarded directly to your email.

#### Tips:

- The new portal is web-based, and no software is needed.
- Pharmacies with dual enrollment (DME and Pharmacy) will be able to bill diabetic supplies as normal NCPDP pharmacy claims but can also bill diabetic supplies through the new portal if desired. Any billing through the new portal will require registration, and training is being offered as above.
- For DME providers—the changes are for diabetic supply products only. Other prosthetic/orthotic/DME products **ARE NOT** affected, and current billing rules apply.





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#### ARKANSAS MEDICAID DUR/DRC BOARD OPEN POSITION

The Arkansas Medicaid Drug Utilization Review Board/Drug Review Committee (DUR/DRC Board) is established under the authority of 42 U.S.C. §1396r–8(g)(3) and 42 CFR § 456.716. The Board is responsible for establishing Prospective Drug Utilization Review (ProDUR) edits, Retrospective Drug Utilization Review (RDUR) criteria, and provider educational interventions. The Board is also responsible for making recommendations to the State concerning the preferred drug list (PDL).

The Board's mission is to improve the quality of care of Arkansas Medicaid beneficiaries receiving prescription drug benefits and conserve program funds while ensuring therapeutically and medically appropriate pharmacy care.

The Board meets quarterly on the 3<sup>rd</sup> Wednesday of January, April, July, and October from 8:30am-12:30pm. The Board is composed of actively practicing physicians and pharmacists. Currently, the Board has 1 open physician position that specializes in rare diseases. If you are interested in serving our Medicaid population, email a CV to Cindi Pearson, PharmD (DUR/DRC Coordinator) at cinnamon.pearson@dhs.arkansas.gov.

**DUR/DRC Board bylaws October 2022** 

#### **VITILIGO**

Written by Susana Granell-Belmutt, RPh. PhD--pharmacist with Arkansas Medicaid

\*Main source of this summary is from UpToDate®. There are not updated society guidelines specific for vitiligo from the USA. There are international and European guidelines which UpToDate® based most of their recommendations.

Vitiligo is an acquired depigmenting disorder pigmentation characterized by the development of well-defined, depigmented macules on the skin. Vitiligo typically presents with asymptomatic depigmented macules and patches, milk or chalk white in color, that lack clinical signs of inflammation. Lesions can appear at any age and anywhere on the body. Biopsies of lesional skin reveal a loss of epidermal melanocytes. Vitiligo affects 0.5%-2% of the global population, without sex differences and affects all age groups. Vitiligo carries a significant disease burden, as evidenced by impairment in quality of life (QOL). Approximately one-third of patients with vitiligo are children, and 70 to 80 percent of adult patients develop vitiligo prior to age 30 years.

#### **ETIOLOGY**

The etiology of vitiligo is unknown. Multiple theories have been proposed for melanocyte destruction in vitiligo. None of the proposed theories are in themselves sufficient to explain the diverse vitiligo phenotypes. The most supported Hypothesis include:

- \*Genetics: Family clustering of vitiligo suggests a genetic basis for the disease. Most of the susceptibility genes associated with vitiligo encode immunoregulatory proteins, whereas several encode melanocyte proteins.
- \*Autoimmunity: Historically, vitiligo has been associated with several autoimmune diseases, including Hashimoto's thyroiditis, Graves' disease, type 1 diabetes mellitus, alopecia areata, pernicious anemia, rheumatoid arthritis, autoimmune polyglandular syndrome, and psoriasis. Studies also suggest that cytotoxic T lymphocytes may play a significant role in melanocyte destruction in vitiligo. Multiple cytokines have also been implicated in the destruction of melanocytes in vitiligo. Several studies have documented increased expression of tumor necrosis factor-alpha, interferon-gamma, interleukin (IL) 10, and IL-17 in lesional skin of patients among others.





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- \*Melanocyte self-destruction hypothesis: The self-destruction hypothesis proposes that melanocytes may be destroyed from an intrinsic increased sensitivity to oxidative stress arising from toxic phenolic compounds formed during the synthesis of melanin.
- \*Oxidative stress hypothesis: Several studies suggest that oxidative stress may be the initial event in the destruction of melanocytes. Severe sunburn, pregnancy, skin trauma, and/or emotional stress may precede the disease onset.

#### CLINICAL CLASSIFICATION

- \*Nonsegmental vitiligo: Patches tend to appear symmetrically on both sides of the body. It can be generalized (random distribution), acrofacial or acral (distal extremities and or the face), mucosal (oral or genital mucosa), universal (complete depigmentation of the skin) or minor (incomplete depigmentation).
- \*Segmental vitiligo: Segmental vitiligo typically occurs on one side of the body. While being the least common type of vitiligo, segmental vitiligo begins during childhood or early adulthood in most cases.
- \*Ocular vitiligo: Melanocytes of the eye, ear, and leptomeninges also may be affected in vitiligo. These asymptomatic lesions do not interfere with visual acuity.

#### ASSOCIATED DISORDERS

- \*Autoimmune diseases: Vitiligo is frequently associated with autoimmune thyroid disease and other autoimmune or immune-mediated diseases, including alopecia areata, psoriasis, type 1 diabetes, rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease, pernicious anemia, linear morphea, myasthenia gravis, discoid and systemic lupus erythematosus, and Sjögren's disease.
- \*Genetic syndromes: Vitiligo is associated with several genetic disorders, which include: Vogt-Koyanagi-Harada, Alezzandrini syndrome and Kabuki syndrome.
- \*Melanoma: Rarely, hypopigmented patches resembling vitiligo may precede a diagnosis of cutaneous melanoma.
- \*Psychosocial issues: Vitiligo may be a psychologically devastating disorder, with a major impact on the patient's self-image and self-esteem. Children with vitiligo may suffer from severe psychologic trauma, resulting in impaired social and emotional development and compromised quality of life later in adulthood.

#### **DIAGNOSIS**

Diagnosis of Vitiligo will include a differential diagnosis from other disorders that are characterized by areas of depigmentation. Vitiligo is NOT associated with scaling or textural changes, although some patients may rarely develop inflammatory vitiligo characterized by raised, erythematous borders. Conditions that should be differentiated from vitiligo include Nevus depigmentosus, Ityriasis alba, Idiopathic guttate hypomelanosis, Tinea versicolor, Halo nevus, Progressive macular hypomelanosis, Lichen sclerosus, chemical leukoderma...among others. Other tests during diagnosis can include blood tests to check for other autoimmune diseases, an eye exam to check for uveitis, and a skin biopsy.





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#### TREATMENT

Factors affecting the approach to treating vitiligo will include the disease severity (% BSA involved) and disease activity (rapid progression or stable). Combination therapies, such as phototherapy plus topical or oral corticosteroids or calcineurin inhibitors appear to be more effective than single therapies.

#### Medications used in the treatment of vitiligo include:

- \*Topical Corticosteroids (support in European and International guidelines): Most studies used potent to very potent corticosteroids once daily, applied topically for 3–6 months. For children, TCS are considered safe if they are continuously used for no more than 2–4 months. For prolonged TCS use, an intermittent scheme and precautions are strongly preferred.
- \*Topical Calcineurin Inhibitors (TCIs) (support on Micromedex and first line in International guidelines): TCIs are first-line treatment in adults and children with limited involvement, especially for lesions on the face, neck or for specific indications. The topical safety profile of TCIs is better when compared to potent TCS, especially concerning the risk of skin atrophy. TCIs are particularly useful in areas where pro-longed use of potent TCS is contraindicated. The efficacy of TCI may be comparable to that of highly potent steroids in both facial and non-facial pediatric vitiligo.

#### \*OPZELURA® (ruxolitinib)

OPZELURA is a cream that contains ruxoltinib, and it is FDA approved for atopic dermatitis and nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Ruxolitinib, a Janus kinase (JAK) inhibitor, inhibits JAK1 and JAK2 which mediate the signaling of several cytokines and growth factors that are important for hematopoiesis and immune function.

Two double-blind, randomized, vehicle-controlled trials of identical design (TRuE V1 and TRuE V2, NCT04052425 and NCT04057573, respectively) enrolled a total of 674 adult and pediatric subjects aged 12 years and older.

Lesions on the face were assessed with the facial Vitiligo Area Scoring Index (F-VASI) and lesions on the total body (including the face) were assessed with the total body Vitiligo Area Scoring Index (T-VASI). Efficacy results for OPZELURA at Week 24:

TruE-V1: 75% improvement on F-VASI was 29.9% for Opzelura versus 7.5% for vehicle and 90% improvement in F-VASI was 15.5% for Opzelura versus 2.2% for vehicle.

TruE-V2: 75% improvement on F-VASI was 29.9% for Opzelura versus 12.9% for vehicle and 90% improvement in F-VASI was 15.4% for Opzelura versus 13.5% for vehicle.

Patients also showed improvement in T VASI in both trials.

Phototherapy was not allowed during the trials. Participants agreed to discontinue all agents used to treat vitiligo from screening through the final safety follow-up visit. Over-the-counter preparations deemed acceptable by the investigator and camouflage makeups were permitted.

\*Systemic corticosteroids: Used for patients with rapidly progressive disease and includes oral prednisone and dexamethasone. This use has support in International guidelines.





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\*Other Systemic immunosuppressants and immunomodulators: Used for patients with rapidly progressive disease and includes cyclosporine, methotrexate, and mycophenolate mofetil, minocycline and ritlecitinib (Litfulo®, indicated for alopecia areata). Support is anecdotical at this point with a handful of peer-reviewed publications. Per guidelines, data remains limited to support their use.

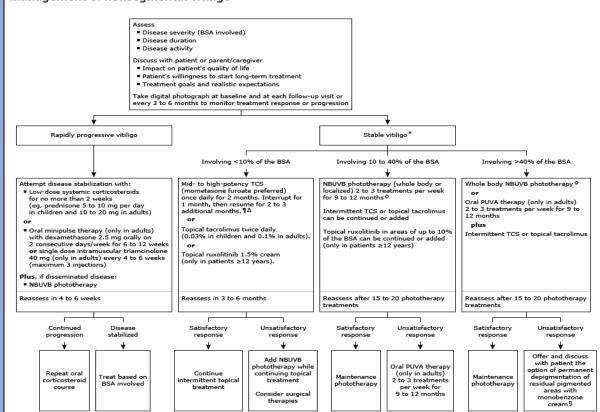
\*Vitamin E, vitamin C, resveratrol, ubiquinone, alpha lipoicacid, panthotenic acid, catalase/superoxide dismutase combination and ginkgo biloba are antioxidants that have been used alone or in combination with phototherapy with the aim of achieving stabilization and repigmentation of vitiligo lesions. Due to differences in patient selection, protocols, mixture of compounds used in trials, poor methodology in some studies using these different combinations of antioxidants and a lack of corroborating reports, there is little or no consensus on their use for vitiligo.

#### NON-PHARMACOLOGICAL TREATMENT OF VITILIGO

\*Phototherapy: In both adults and children in whom systemic corticosteroids are contraindicated, targeted UVB phototherapy or NBUVB phototherapy may be used alone to stabilize active vitiligo. NBUVB is administered two to three times weekly. NBUVB requires six months to one year of treatment to achieve optimal outcomes for stabilization and repigmentation.

# USEFUL ALGORITHMS \*NON SEGMENTAL VITILIGO

algorithm from UpToDate® Management of nonsegmental vitiligo - UpToDate Management of nonsegmental vitiligo







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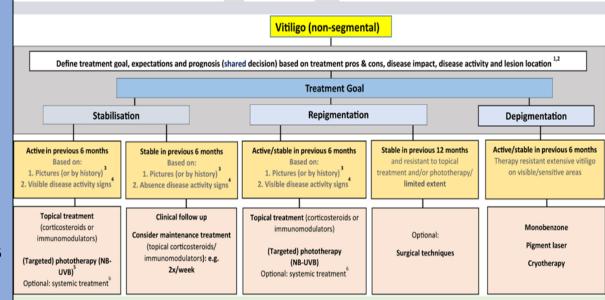
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- \* Vitiligo is defined as "stable" if no increase in size of existing lesions and absence of new lesions are noted in the previous 3 to 6 months.
- ¶ An alternative regimen for TCS involves daily application for 14 days followed by an interval of 14 days.
- Δ Monitor closely (e.g., every 6 weeks) for local adverse effects of TCS (e.g., skin atrophy, telangiectasias, hypertrichosis, acneiform eruptions).
- ♦ Phototherapy is not indicated for young children.
- § Refer to UpToDate® topics for additional details on depigmentation.

Algorithm form the International Guidelines <u>Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task</u> Force Part 1: towards a new management algorithm (wiley.com)



#### General remarks:

- Use algorithm in combination with information/recommendations provided in the text.
- Provide information : avoidance Koebner's phenomenon, cosmetic skin camouflage, use of sunscreens (consider information leaflet)
- Consider and discuss the risk-benefit ratio in particular for systemic treatments, combination therapies (e.g. topical immunomodulators/systemic treatment + UV) and prolonged treatment
- 1 Other aspects for shared decision: e.g. skin type, disease duration, presence comorbidities, extent on visible/sensitive areas, geographical region.
- 2 Explain relation between body location and expected results ('best' to 'worse': face>other body areas> hands/feet); Explain the treatment expectations and limitations.
- 3 Active = new lesions or increase of existing lesions; Stable= no new lesions or no increase of existing lesions.
- 4 Clear presence of confetti-like depigmentations, hypochromic borders/areas or Koebner's phenomenon (for assessment consider e.g. Br J Dermatol. 2020;183(5):883-890; www.vitiligo-calculator.com) 5 NB-UVB and combination therapy preferred (e.g. phototherapy + topical corticosteroids).
- 6 Oral steroid mini pulse (most investigated) and alternatives reported: methotrexate, cyclosporine, azathioprine, minocycline and Janus Kinase (JAK) inhibitors (currently investigated).

#### \*SEGMENTAL VITILIGO

Topical corticosteroids, topical calcineurin inhibitors, or targeted phototherapy are the first-line therapies for limited segmental vitiligo. For patients with stable, segmental vitiligo that does not respond to topical or light therapies, autologous grafting is a second-line option.





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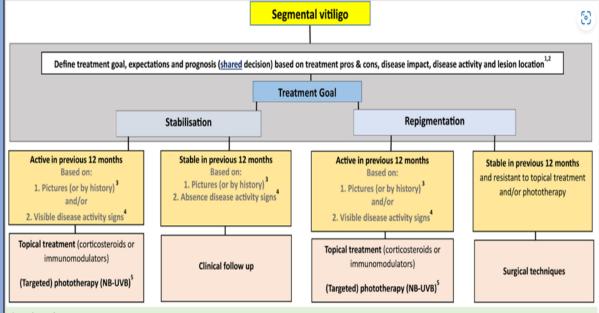
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  - 1) Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task Force Part 1: towards a new management algorithm (wiley.com)
  - 2) Vitiligo: Pathogenesis, clinical features, and diagnosis UpToDate
  - 3) Vitiligo: Diagnosis, Treatment, and Steps to Take (nih.gov)
  - 4) Vitiligo: Management and prognosis UpToDate
  - 5) <u>DailyMed OPZELURA- ruxolitinib cream (nih.gov)</u>
  - 6) Topical Ruxolitinib Evaluation in Vitiligo Study 2 (TRuE-V2) Study Results ClinicalTrials.gov
  - 7) Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the international Vitiligo Task Force—Part 2: Specific treatment recommendations (wiley.com)
  - 8) <u>Drug Result Page Quick Answers Dosing/Administration Non-FDA Uses</u> (micromedexsolutions.com)





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NEW FDA APPROVED MEDS 2024	INDICATION	AR MEDICAID COVERAGE
Rivfloza™	Treat primary hyperoxaluria type 1	Manual review with criteria determined by the DUR Board
Agamree®	Treatment of Duchenne Muscular Dystrophy	Manual review with criteria determined by the DUR Board
Filsuvez®	Treat dystrophic and junctional epidermolysis bullosa	Manual review with criteria determined by the DUR Board
Duvyzat™	Treat Duchenne Muscular Dystrophy	Manual review with criteria determined by the DUR Board
Winrevair™	Treat pulmonary arterial hypertension	Nonpreferred in the PAH class
Rezdiffra™	Treat noncirrhotic nonalcoholic steatohepatitis	Manual review with criteria determined by the DUR Board
Vafseo®	Anemia due to CKD	Manual review with criteria determined by the DUR Board
Opsynvi™	Treat pulmonary arterial hypertension	Nonpreferred in the PAH class
Tyenne®	Biosimilar to Actemra®	Nonpreferred in the targeted immunomodulators class
Eohilia™	Treat eosinophilic esophagitis	Point-of-sale edit looking for proper diagnosis
Simlandi®	Biosimilar to Humira®	Nonpreferred in the targeted immunomodulators class
Jubbonti®	Biosimilar to Prolia®	Nonpreferred in the osteoporosis class with Prolia® criteria
Wyost®	Biosimilar to Xgeva®	Manual review with Xgeva® criteria
Tryvio™	Treat hypertension	Nonpreferred in the HTN class with criteria
Voydeya™	Treat paroxysmal nocturnal hemoglobinuria	Manual review with criteria determined by the DUR Board
Anktiva®	Bladder Cancer	Excluded in pharmacy; medical review only
Ojemda™	Pediatric low-grade glioma	Manual review based on the oncology policy
Xolremdi™	WHIM Syndrome	Manual review with criteria determined by the DUR Board
lmdelltra™	Extensive stage SCLC	Excluded in pharmacy; medical review only
Rytelo™	Myelodysplastic syndrome	Excluded in pharmacy; medical review only
Iqirvo®	Primary biliary cholangitis	Manual review with criteria determined by the DUR Board
Sofdra	Hyperhidrosis	Manual review with criteria determined by the DUR Board
Piasky	Paroxysmal nocturnal hemoglobinuria	Manual review with criteria determined by the DUR Board





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USEFUL LINKS/PHONE NUMBERS

DHS webpage

(contains official notices and other information for providers and clients)

https://humanservices.arkansas.gov/divisions-shared-services/medical-services/helpful-information-for-providers/

DHS provider manuals

https://humanservices.arkansas.gov/divisions-shared-services/medical-services/helpful-information-for-providers/manuals/

Arkansas Foundation for Medical Care (AFMC)

If you are having billing issues for vaccines and other medical professional claims, contact AFMC or your outreach specialist.

https://www.afmc.org/

https://medicaid.afmc.org/services/arkansas-medicaid-management-information-system

**AFMC PHONE:** 479-649-8501 **AFMC FAX:** 479-649-0799

DME billing assistance

Kara Orvin phone: 501-630-6064 Kara.L.Orvin@dhs.arkansas.gov

Third Party Liability (TPL) phone: 501-537-1070

Provider Assistance Center (PAC)

For questions about individual or pharmacy enrollment, please contact the provider assistance center.

Provider Assistance Center (PAC) in Arkansas: 800-457-4454 Provider Assistance Center (PAC) from out of state: 501-376-2211

Opioid guidance

- https://arkansas.magellanrx.com/client/documents
- https://www.cdc.gov/drugoverdose/
- https://www.samhsa.gov/medication-assisted-treatment
- The Dangers Of Mixing Benzodiazepines With Opiates Opioid Treatment
- https://www.rehabs.com/blog/the-polypharmacy-overdose-a-killer-trend/
- https://narcansas.com/
- https://afmc
  - analytics.maps.arcgis.com/apps/MapSeries/index.html?appid=2977d338de974451af 5ce8ff24d2a30c
- https://www.cdc.gov/overdose-prevention/

#### DUR BOARD MEETING DATES

July 17, 2024 October 16, 2024 January 15, 2025 April 16, 2025