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HEALTH ALERT NETWORK | HEALTH ADVISORY | January 25, 2022

HHS update on COVID-19 therapeutics

(Below is a message from the U.S. Department of Health and Human Services)

The prevalence of COVID-19 variants remains dynamic, and the U.S. Department of Health and Human Services (HHS) actively assesses data on a continuous basis to adjust COVID-19 therapeutics allocation guidelines as required.

When we learned of Omicron, we immediately reviewed our existing monoclonals and available data on whether they would work against the new variant and learned that two of them – bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) – are not effective against Omicron. Subsequently, both Lilly and Regeneron have said their products are not likely to be effective against Omicron, and several independent studies have shown this as well.

CDC data released last week confirms that Omicron is the overwhelmingly dominant variant of concern (VOC) in the United States at a prevalence of greater than 97.8% in all regions and nationally greater than 99%. Private sector data points to Omicron's dominance as well. For example, Walgreens estimates that every state is above 95% Omicron. HHS has also communicated with many state health officials over the past week, who have shared this is the reality they are seeing on the ground as well.

In light of these facts, the FDA today updated the Emergency Use Authorization (EUA) fact sheets for two COVID-19 monoclonal antibody treatments: Lilly's bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV). FDA now says these two treatments are not currently authorized for use anywhere in the U.S., due to the prevalence of Omicron. FDA is encouraging healthcare providers to choose authorized treatment options with activity against circulating variants in their state, territory, or U.S. jurisdiction. This follows action last week by the National Institutes of Health (NIH) to update its clinical guidelines to recommend against the use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) at this time.

As a result of the extremely high prevalence of Omicron and recent guidance from FDA and NIH, **we will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) in today's allocations for COVID-19 therapeutics.**

Jurisdictions, providers and patients should be aware that we have more treatments that do work against Omicron available than ever before, including oral and IV antivirals in addition to the GSK/Vir monoclonal antibody (Sotrovimab). Sotrovimab, Evusheld, Paxlovid and Molnupiravir are included in today's allocations; attached are the jurisdiction-by-jurisdiction allocated amounts.

We are committed to making sure that, if Americans get sick with COVID-19, they are offered treatments that work. It is critically important we are giving effective therapies to patients, and HHS will continue to provide effective treatments to states at no cost.

Thank you for your continued partnership in the COVID-19 response. Please contact us at COVID19Therapeutics@hhs.gov should you have questions regarding this update.

COVID-19 Therapeutics Allocations
Jan 24-30, 2022
Units = patient courses

Jurisdiction	Total Allocation	Sotrovimab	Evusheld	Molnupiravir	Paxlovid
Alaska	1212	144	168	720	180
Alabama	8368	1248	1080	4840	1200
Arkansas	4928	576	672	2940	740
American Samoa	0	0	0	0	0
Arizona	11544	1512	1512	6820	1700
Bureau of Prisons	84	36	48	0	0
California	63436	6768	8568	38540	9560
Colorado	8880	816	1224	5480	1360
Connecticut	5784	408	816	3640	920
District of Columbia	1208	120	168	740	180
Delaware	1560	144	216	960	240
DOD	6796	396	0	5120	1280
DOS	100	0	0	40	60
Florida	34216	3216	4680	21080	5240
Micronesia	0	0	0	0	0
Georgia	16028	1296	2232	10000	2500
Guam	0	0	0	0	0
Hawaii	2424	288	336	1440	360
HRSA	75000	0	0	60000	15000
Iowa	4940	384	696	3080	780
ICE	76	36	0	20	20
Idaho	2552	192	360	1600	400
IHS	5400	1500	600	2640	660
Illinois	20496	1824	2832	12680	3160
Indiana	10592	1008	1464	6500	1620
Kansas	4720	576	624	2820	700
Kentucky	7348	864	984	4400	1100

Louisiana	7404	672	1032	4560	1140
Massachusetts	11356	1056	1560	7000	1740
Maryland	9304	480	1344	5980	1500
Maine	2192	120	312	1400	360
Marshall Island	0	0	0	0	0
Michigan	16016	1368	2208	9960	2480
Minnesota	8816	792	1224	5440	1360
Missouri	9748	864	1344	6040	1500
Northern Mariana Islands	0	0	0	0	0
Mississippi	4788	480	648	2920	740
Montana	1680	120	240	1060	260
North Carolina	16728	1872	2256	10080	2520
North Dakota	**1272**	**144**	**168**	**760**	**200**
Nebraska	2996	288	408	1840	460
New Hampshire	2288	216	312	1400	360
NIH	140	24	96	0	20
New Jersey	14008	960	1968	8860	2220
New Mexico	3396	360	456	2060	520
Nevada	4892	624	648	2900	720
New York	31572	2376	4416	19840	4940
Ohio	18544	1536	2568	11560	2880
Oklahoma	6128	504	864	3800	960
Oregon	6624	528	936	4120	1040
Pennsylvania	20544	1464	2880	12960	3240
Puerto Rico	5400	312	768	3460	860
Palau	0	0	0	0	0
Rhode Island	2076	432	264	1100	280
South Carolina	8384	1080	1104	4960	1240
South Dakota	1396	144	192	840	220
Tennessee	10804	1056	1488	6600	1660
Texas	42852	4032	5880	26380	6560
Utah	4596	552	624	2740	680
Virginia	13404	1032	1872	8400	2100
VHA	13056	396	1920	8600	2140
U.S. Virgin Islands	304	120	24	120	40
Vermont	1128	120	168	660	180
Washington	11720	1008	1632	7260	1820
Wisconsin	9840	1344	1296	5760	1440

West Virginia	3104	312	432	1880	480
Wyoming	1004	120	144	580	160
Totals	**627196**	**52260**	**74976**	**399980**	**99980**

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