COVID-19 situation in RRT patients and LAAB in Dialysis patients

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COVID-19 in dialysis patients

• Global prevalence : 5 – 25%

mortality : 20 – 30% or 4 times of nondialysis patients

- CKD → immunological disorder → rapidly dead (inadequate infection control in the early phase of the disease
- 10 50% of dialysis patients \rightarrow asymptomatic infection
- Dialysis patients delay viral clearance : median time from admission to -ve RTPCR = 18 days or 20 days after symptoms → more longer quarantine times until viral < 100,000 copies/ml or Ct > 28 - 31
- Lower antibody level after vaccination

Kidney Med (2021). 3(4): 619-634. Kidney International (2022) 101, 883–894

Anti-SARS-CoV-2 Spike Protein S1 Receptor-Binding Domain Antibody to

An Inactivated Whole-virus SARS-CoV-2 Vaccination in End-stage Kidney

Disease Patients: An Initial Report

Sarinya Boongird, MD, Piyatida Chuengsaman, MD, Salinnart Phanprasert, MD, Rungthiwa Kitpermkiat, MD, Montira Assanatham, MD, Arkom Nongnuch, MD, Sasisopin Kiertiburanakul, MD, MHS, Kumthorn Malathum, MD, Angsana Phuphuakrat, MD, PhD, Chavachol Sethaudom, MSc, Jackrapong Bruminhent, MD



COVID-19 in chronic HD & PD patients (Thailand 2020, 1st pandemic)

- Chronic hemodialysis patients infected with SARS-CoV-2
 - Total 5 casessurvive 5 casesTotal HD 70,000cases
- Chronic peritoneal dialysis patients infected with SARS-CoV-2
 - Total 1 casesurvive 1 caseTotal PD 30,000cases
- Kidney transplantation infected with SARS-CoV-2

Total **3** casessurvive **3** casesTotal KT **6,000** cases

Prevalence and incidence of COVID-19 in Dialysis patients (Thailand 2021, 2nd pandemic)

	Total	COVID-19	Dead
 Thailand 			
GP	66,000,000	1,391,477 (2%)	14,671 <mark>(1%)</mark>
ВКК	8,000,000	335 <i>,</i> 639 (4%)	5,682 (1.7%)
PD	27,556	517 (2%)	167 (>32%)
ВКК	1,728	237 (13%)	86 (>36%)
HD	130,000	>3,000 (>2%)	>500 (>10%)
ВКК	12,139	>1,000 (>8%)	137/647 (20%)

Prevalence and incidence of COVID-19 in Dialysis patients (Thailand 2022, 3rd pandemic)

	<u>Total</u>	COVID-19	Dead
 Thailand 			
PD	27,000	1,152 (5%)	78 (>7%)
ВКК	1,700	178 (10%)	7 (>5%)
HD	170,000	>5,000 (>3%)	>100 (>2%)
ВКК	15,000	1,000 (>7%)	3/500 <mark>(1%)</mark>



Prevalence of Dialysis patients

ความชุกผู้ป่วยที่ได้รับการบำบัดทดแทนไต (Prevalence of RRT)

ข้อมูลสมาคมโรคไตแห่งประเทศไทยพบว่าความชุกของจำนวนผู้ป่วยที่ได้รับการบำบัดทดแทนไตด้วยวิธีฟอกเลือด ล้าง ไตทางช่องท้อง และปลูกถ่ายไตแสดงในตารางที่ 1

Years	Hemodialysis	Peritoneal dialysis	Kidney transplantation*	Total	จำนวน ประชากร**	ความชุก (คน) ต่อ 1 ล้าน ประชากร
2016	72,622	20,216	8,132	100,970	65,931,550	1,531
2017	84,910	24,001	5,360	114,271	66,188,503	1,726
2018	97,265	26,070	5,652	128,987	66,413,979	1,942
2019	114,262	30,869	6,212	151,343	66,558,935	2,274
2020	129,724	34,467	6,583	170,774	66,186,727	2,580

/2022

200,000+

Causes of ESRD





Causes of ESRD

สาเหตุของภาวะไตเรื้อรังที่ได้รับการบำบัดทดแทนไตของผู้ป่วยในปี พ.ศ. 2563

พบว่าสาเหตุหลักของผู้เข้ารับการบำบัดทดแทนไตในปี พ.ศ. 2563 ได้แก่ ความดันโลหิตสูง และเบาหวาน ดังแสดง เป็นร้อยละในตารางที่ 3

Disease	%
Hypertension	42.30
Diabetic nephropathy	41.50
Unknown	8.49
Presumed GN(No biopsy)	1.73
Obstructive nephropathy	1.25
Lupus nephritis	1.20
Polycystic kidney disease	1.19
Glomerulonephritis : Biopsy-proven(มีผล Kidney biopsy)	0.77



การกระจายของผู้ป่วยที่ได้รับการบำบัดทดแทนไตในแต่ละช่วงอายุในปี พ.ศ. 2562-2563 ผู้ป่วยที่ได้รับการบำบัดทดแทนไตส่วนใหญ่อยู่ในอายุช่วง 45-64 ปี และผู้มีอายุ 65-74 ปี เป็นลำดับถัดมาดังแสดงใ รูปที่ 1





6. การประเมินโรคร่วมด้วย Charlson Comorbidity Index (CCI) Score

ดัชนีโรคร่วมชาร์ลสัน (Charlson comorbidity index: cci) ซึ่งประเมินระดับความรุนแรงของโรคร่วม โดยเป็นการให้ น้ำหนักคะแนน (weighted score) ต่อโรคร่วมบางกลุ่มโรคที่มีในผู้ป่วยแต่ละราย โดยพบว่าในผู้ป่วยรายใหม่ในปี พ.ศ. 2563 ส่วนใหญ่มีค่า score อยู่ในช่วง 4 - 7

	Score	ร้อยละของผู้ป่วย (%)
	17	<0.01
	16	<0.01
	15	0.01
	14	0.02
	13	0.04
	12	0.07
60%	11	0.17
	10	0.65
	9	2.71
	8	7.11
	7	13.55
	6	16.96
	5	18.73
	4	16.80
	3	11.51
	2	11.68
	1	-
	0	-

Comorbidity score

ดารางที่ 6 แสดงผลการประเมินของโรคร่วมด้วย Charlson Comorbidity Index



Performance Scale

7. การประเมินสภาวะของผู้ป่วยด้วย Karnofsky Performance Status (KPS) Score

จากการประเมินสภาพผู้ป่วยในปี พ.ศ. 2563 ที่ได้รับการบำบัดทดแทนไตพบว่าส่วนใหญ่ร้อยละ 43.6 มีค่า KPS Score

เท่ากับ 90

		ร้อยละของผู้ป่วย	Table 1. Karnofsk	y Performance Scal
	Score	(%)	Score (category)	Karnofsky
	100	(70)	100	Normal; no compl disease.
	90	13.6	90	Able to carry on n signs or symptoms
90%	90	45.0	80	Normal activity w symptoms of disea
		9.0	70	Care for self; unal activity or to do ac
	70	0.7	60	Requires occasion to care for most of
	60	11.4	50	Requires consider frequent medical of
	50	5.3	40	Disabled; requires assistance.
	40	3.6	30	Severely disabled; necessary; active s
	30	0.3	20	necessary. Very sick; hospita
	20	0.4		active supportive t Moribund; fatal pr
	10	0.5	0	rapidly. Dead

Score (category)	Karnofsky
100	Normal; no complaints; no evidence of
100	disease.
90	Able to carry on normal activity; minor
70	signs or symptoms.
<u>00</u>	Normal activity with effort; some signs or
80	symptoms of disease.
70	Care for self; unable to carry on normal
/0	activity or to do active work.
60	Requires occasional assistance but is able
60	to care for most of his needs.
50	Requires considerable assistance and
30	frequent medical care.
40	Disabled; requires special care and
40	assistance.
	Severely disabled; hospitalization
30	necessary; active supportive treatment is
	necessary.
20	Very sick; hospitalization necessary;
20	active supportive treatment is necessary.
10	Moribund; fatal processes progressing
10	rapidly.
0	Deed



10. สิทธิการรักษาพยาบาลในผู้ป่วยที่ได้รับการบำบัดทดแทนไต

สิทธิการรักษาพยาบาล	2018	2019	2020 2022
ประกันสุขภาพทั่วหน้า	32.32%	37.39%	39.50% 55%
ราชการ	23.75%	20.62%	22.81% 25%
ประกันสังคม	19.74%	18.21%	19.31% 20%
ชำระเอง	14.90%	13.63%	15.53%
รัฐวิสาหกิจ	2.15%	2.22%	2.1296
ประกันชีวิต	0.20%	0.50%	0.6096
องค์กรการกุศลออกให้	0.23%	0.1396	0.13%

ดารางที่ 10 แสดงสิทธิการรักษาพยาบาลในผู้ป่วยที่ได้รับการบำบัดทดแทนไต



14. การกระจายด้วของหน่วยไตเทียม Hemodialysis แบ่งตามภูมิภาค

	2011	2018	2019	2020
223(32.4%)	236(32.6%)	256(32.7%)	270(33.5%)	288 (33.7%)
78(11.3%)	82(11.3%)	88(11.3%)	83(10.3%)	86 (10.1%)
33(4.8%)	35(4.8%)	35(4.5%)	37(4.6%)	36 (4.2%)
52(7.6%)	56(7.7%)	62(7.9%)	64(7.9%)	70 (8.2%)
176(25.6%)	184(25.4%)	199(25.4%)	199(24.7%)	214 (25.0%)
60(8.7%)	60(8.3%)	67(8.6%)	80(9.9%)	81 (9.4%)
66(9.6%)	70(9.7%)	75(9.6%)	73(9.1%)	80 (9.5%)
688(100%)	723(100%)	782(100%)	806(100%)	855(100%)
	223(32.4%) 78(11.3%) 33(4.8%) 52(7.6%) 176(25.6%) 60(8.7%) 66(9.6%) 688(100%)	223(32.4%) 236(32.6%) 78(11.3%) 82(11.3%) 33(4.8%) 35(4.8%) 52(7.6%) 56(7.7%) 176(25.6%) 184(25.4%) 60(8.7%) 60(8.3%) 66(9.6%) 70(9.7%) 688(100%) 723(100%)	223(32.4%) 236(32.6%) 256(32.7%) 78(11.3%) 82(11.3%) 88(11.3%) 33(4.8%) 35(4.8%) 35(4.5%) 52(7.6%) 56(7.7%) 62(7.9%) 176(25.6%) 184(25.4%) 199(25.4%) 60(8.7%) 60(8.3%) 67(8.6%) 66(9.6%) 70(9.7%) 75(9.6%) 688(100%) 723(100%) 782(100%)	223(32.4%) 236(32.6%) 256(32.7%) 270(33.5%) 78(11.3%) 82(11.3%) 88(11.3%) 83(10.3%) 33(4.8%) 35(4.8%) 35(4.5%) 37(4.6%) 52(7.6%) 56(7.7%) 62(7.9%) 64(7.9%) 176(25.6%) 184(25.4%) 199(25.4%) 199(24.7%) 60(8.7%) 60(8.3%) 67(8.6%) 80(9.9%) 66(9.6%) 70(9.7%) 75(9.6%) 73(9.1%) 688(100%) 723(100%) 782(100%) 806(100%)

ดารางที่ 13 แสดงการกระจายตัวของหน่วยไตเทียม Hemodialysis แบ่งตามภูมิภาค



17. การกระจายตัวของหน่วยล้างไตทางช่องท้อง (Peritoneal dialysis) แบ่งตามภูมิภาค

ภูมิภาค	2016	2017	2018	2019	2020
กรุงเทพมหานครและปริมณฑล	27(19.4%)	28(19.3%)	39(20.2%)	39(19.6%)	38(18.9%)
ภาคกลาง	23(16.5%)	25(17.2%)	29(15.0%)	29(14.6%)	29(14.4%)
ภาคตะวันตก	7(5.0%)	7(4.8%)	9(4.7%)	10(5.0%)	10(5.0%)
ภาคตะวันออก	6(4.3%)	8(5.5%)	13(6.7%)	16(8.0%)	17(8.5%)
ภาคตะวันออกเฉียงเหนือ	44(31.7%)	45(31.0%)	58(30.1%)	59(29.6%)	60(29.9%)
ภาคเหนือ	14(10.1%)	14(9.7%)	20(10.4%)	22(11.1%)	22(10.9%)
ภาคใต้	18(12.9%)	18(12.4%)	25(13.0%)	24(12.1%)	25(12.4%)
รวม	139(100%)	145(100%)	193(100%)	199(100%)	201(100%)

ตารางที่ 15 แสดงการกระจายตัวของหน่วยล้างไตทางช่องท้อง (Peritoneal dialysis) แบ่งตามภูมิภาค



Death rate

30. ผลการรักษา (Outco	ome) ในปี 2563	
	·	

ผลการรักษา (Outcome)	ร้อยละของผู้ป่วยที่สินสุดหรือ เปลี่ยนแปลงการรักษา
HD	
 HD-HD (ไม่เปลี่ยนแปลงการรักษา) 	96.2
● HD → PD (เปลี่ยนจาก HD เป็น PD)	2.1
 HD -> KT (ได้รับการปลูกถ่ายไต) 	1.7
PD	
 PD-PD (ไม่เปลี่ยนแปลงการรักษา) 	98.9
 PD → HD (เปลี่ยนจาก PD เป็น HD) 	1.0
 PD → KT (ได้รับการปลูกถ่ายไต) 	0.1
Change center	12.8
Loss FU	5.7
 Financial 	3.16
Voluntary	19.8
Other	77.0
Dead	22.7

ดารางที่ 27 แสดงร้อยละของผู้ป่วยที่สินสุดหรือเปลี่ยนแปลงการรักษา ในปี 2563

Summary of COVID-19 in Thai RRT patients 2022

- Total RRT patients 200,000 cases (HD 170,000, PD 23,000, KT 7,000)
 >50% of cases in Bangkok, Northeastern part had many comorbidities, but high performance
- Prevalence of COVID-19 in Thai dialysis patients 5 10%, dead 5 - 10%
 - > 80% have got 3 doses of vaccines (> 1 mRNA vaccines)

Anti–SARS-CoV-2 Antibodies

Convalescent plasma (CP)

early in the disease course with potent, high-titer Abs no benefit in outpatients (C3PO study)

• Hyperimmune globulin (HIG)

highly purified anti–SARS-CoV-2 Abs from multiple donors who have recovered from COVID-19

modest but statistically nonsignificant outcomes

Monoclonal antibody (mAbs)

targeting the spike protein

bamlanivimab, BRII-196 plus BRII-198 showed unfavorable outcomes sotrovimab modest but statistically nonsignificant outcomes

CP, mAbs and HIG administered after multiple days of illness may not be useful New variant of SARS-CoV-2???

Anti–SARS-CoV-2 antibodies : outpatient

- Sotrovimab (4/5/2022), REGEN-COV, bamlanivimab and etesevimab, casirivimab-imdevimab : not effective for treatment of mild to moderate COVID-19 and postexposure prevention in omicron variant
- Bebletovimab : treatment of mild to moderate COVID-19 (active against omicron sub lineages)
- Tixagevimab-cilgavimab (Evusheld) : preexposure prophylaxis (active against omicron sub lineages)

Monoclonal antibodies protect against COVID-19

- irrespective of immune system status and provide rapid protection are potential options for Covid-19 immunoprophylaxis
- Some combinations of monoclonal antibodies are already in use against Covid-19 through emergency or temporary authorization for preexposure prophylaxis
 - postexposure prophylaxis or
 - treatment of mild-to moderate disease

Activity of Tixagevimab/Cilgavimab against the Omicron variant of SARS-CoV-2 in a hamster model



Omicron virus requires about 20-times more antibodies in plasma than the ancestral B.1 strain (G614) virus to achieve a similar drug efficacy in reducing lung infectious titers

EuropePMC; 2022, March.

Tixagevimab/Cilgavimab: LAAB Combination



- 2 human mAbs binding 2 distinct epitopes³
- Highly potent⁴
- Retained neutralizing activity against variants of concern³
- Extended half-life (YTE modification)⁵
- Favorable safety profile⁶
- Efficacy was shown for pre-exposure prophylaxis in high-risk populations⁵

Some of the information provided is based off a preprint research paper that has not been peer reviewed.

C1q = complement component 1q; mAb = monoclonal antibody; FcR = fragment crystallizable region; LAAB = long-acting antibody; RBD = receptor-binding domain; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TM = triple modification; YTE = M252Y/S254T/T256E.

1. Sehnal D et al. *Nucleic Acids Res.* 2021;49:W431-W437; 2. Protein Data Bank. https://www.rcsb.org/. 7L7E. Accessed November 10, 2021; 3. Loo YM et al. Preprint published online. *medRxiv.* 2021; 4. Zost SJ et al. *Nature.* 2020;584:443-4493. 5. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021; 6. Levin M et al. Presentation at: IDWeek 2021; September 29-October 3, 2021; virtual conference.

The NEW ENGLAND JOURNAL of MEDICINE

Preexposure, N = 5197, unvaccinated, Asia 3%, CKD 5%, immunocompromised 0.5%, →2021 May one each of 150 mg tixagevimab and 150 mg cilgavimab

ORIGINAL ARTICLE

Intramuscular AZD7442 (Tixagevimab– Cilgavimab) for Prevention of Covid-19

M.J. Levin, A. Ustianowski, S. De Wit, O. Launay, M. Avila, A. Templeton, Y. Yuan,
S. Seegobin, A. Ellery, D.J. Levinson, P. Ambery, R.H. Arends, R. Beavon, K. Dey,
P. Garbes, E.J. Kelly, G.C.K.W. Koh, K.A. Near, K.W. Padilla, K. Psachoulia,
A. Sharbaugh, K. Streicher, M.N. Pangalos, and M.T. Esser,
for the PROVENT Study Group*

Table 3. Primary End Point and Key Supportive Efficacy Analyses in the Full Preexposure Analysis Set*							
First Case of SARS-CoV-2 RT-PCR-Positive Symptomatic Illness	Primary Analysis				Median 6-Mo Follow-up †		
	AZD7442 (N= 3441)	Placebo (N=1731)	Relative Risk Reduction % (95% CI)	PValue	AZ D7442 (N= 3441)	Placebo (N = 1731)	Relative Risk Reduction % (95% CI)
	no. of partid pants (%)			no. of participants (%)			
Primary end point first case of illness, with data censored at unblinding or receipt of Covid-19 vaccine	8 (0.2)	17 (1.0)	76.7 (46.0-90.0)	<0.001	11 (0.3)	31 (1.8)	82.8 (65.8-91.4)
Key supportive analyses							
First case of illness, regardless of unblind- ing or receipt of Covid-19 vaccine	10 (0.3)	22 (1.3)	77.3 (52.0-89.3)	⊲0.001	20 (0.6)	44 (2.5)	77.4 (61.7-86.7)
First case of illness, in duding all deaths, with data censored at unblinding or receipt of Covid-19 vaccine	12 (0.3)	19 (1.1)	68.8 (35.6-84.9)	0.002	18 (0.5)	36 (2.1)	75.8 (5 7.3–86.2)



Tixagevimab/Cilgavimab Did Not Meet the Primary Endpoint of Postexposure Prevention of Symptomatic COVID-19 Compared With Placebo¹

one each of 150 mg tixagevimab and 150 mg cilgavimab

Summary of the results

202	Population ^{N+1121,} → 2021 April	Baseline	Onset of case post- dose	Number of cases/ number of participants		Relative risk
8	Unvaccinated adults with confirmed exposure to a person with a case of SARS-CoV-2 within the past 8 days (N=1121) ^a	subgroup		TIXA/CILGA (300-mg IM)	Placebo	reduction (95% CI)
	Safety summary	All participants (primary endpoint)	All cases	23/749	17/372	33% reduction ^b (95% Cl, -26 to 65)
TIXA/CIL 6-month	TIXA/CILGA had a favorable safety profile over the extended 6-month follow-up ²	PCR-negative° (preplanned subgroup analysis)	All cases	6/715	11/358	73% reduction (95% Cl, 27 to 90)
	Publication	PCR-negative [®]	≤7 days	5/715	5/358	51% reduction (95% Cl, -71 to 86)
	Full results from STORM CHASER will be submitted for publication in a peer-reviewed medical journal	subgroup analysis)	>7 days	1/710	6/353	92% reduction (95% Cl, 32 to 99)

This analysis focused on the effect of TIXA/CILGA on the post-exposure prevention of symptomatic COVID-19, and not on the pre-exposure prevention or treatment of COVID-19

*All participants had a negative SARS-CoV-2 antibody test on the day of dosing to exclude prior infection, and a nasopharyngeal swab was also collected and subsequently analysed for SARS-CoV-2 by PCR to detect virus; *Not statistically significant; functudes 974 participants (15 cases) confirmed PCR-negative at baseline and 99 participants (2 cases) with PCR status missing at baseline. CI = confidence interval; COVID-19 = coronavirus disease 2019; IM = intramuscular; PCR = polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TIXA/CILGA = tixagevimab/cilgavimab.

1. AstraZeneca Pharmaceuticals LP press release. Published June 15, 2021; 2. Levin MJ et al. Abstract presented at: ECCMID 2022; April 23-26, 2022; Lisbon, Portugal. Abs 4789.

Efficacy and safety of intramuscular administration of tixagevimab-cilgavimab for early outpatient treatment of COVID-19 (TACKLE): a phase 3, randomised, double-blind, placebo-controlled trial

Hugh Montgomery, F D Richard Hobbs, Francisco Padilla, Douglas Arbetter, Alison Templeton, Seth Seegobin, Kenneth Kim, Jesus Abraham Simón Campos, Rosalinda H Arends, Bryan H Brodek, Dennis Brooks, Pedro Garbes, Julieta Jimenez, Gavin C K W Koh, Kelly W Padilla, Katie Streicher, Rolando M Viani, Vijay Alagappan, Menelas N Pangalos, Mark T Esser, on behalf of the TACKLE study group

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Mild to Moderate COVID-19, N = 1014, unvaccinated High risk of progression : CKD 2%, immunocompromised 5% 2021 Jan – July

one each of 300 mg tixagevimab and 300 mg cilgavimab

	Population	Tixagevimab– cilgavimab	Placebo	RR reduction (95% CI)	pvalue
Primary efficacy endpoints and supp	oortive estimands				
Primary endpoint: severe COVID-19 or death from any cause through to day 29	Modified full analysis set*	18/407 (4%)	37/415 (9%)	50.5% (14.6-71.3)	0.0096
Secondary and exploratory endpoin	ts				
Secondary endpoint: prevention of respiratory failure	Modified full analysis set	3/405 (1%)	11/412 (3%)	71.9% (0.3–92.1)	0.036
Exploratory: hospitalisation for COVID-19 including complications through to day 29	Modified full analysis set	17/413 (4%)	40/421 (10%)		

Tixagevimab–cilgavimab for treatment of patients hospitalised with COVID-19: a randomised, double-blind, phase 3 trial

ACTIV-3–Therapeutics for Inpatients with COVID-19 (TICO) Study Group* \dagger

Moderate to severe COVID-19, N = 1417, 75% unvaccinated High risk of progression : CKD 9-10%, immunocompromised 8-10% 2021 Feb – Sep (no organ failure or high-flow O2 use) **one each of 300 mg tixagevimab and 300 mg cilgavimab Remdesivir (60+%) + corticosteroid (70+%)**

	Tixagevimab- cilgavimab group (n=710)	Placebo group (n=707)	Rate or hazard ratio* (95% CI)	p value
Full cohort				
Co-primary, sustained recovery up to day 90†‡	617 (89%)	595 (86%)	1.08 (0.97-1.20)	0-21
Censored	34 (5%)	31 (4%)		
Died before sustained recovery	59 (8%)	81 (11%)		
Death up to day 90	61 (9%)	86 (12%)	0.70 (0.50-0.97)	0-032



COVID-19 = coronavirus disease 2019; IM = intramuscular; IV = intravenous; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

1. Study NCT04625725. ClinicalTrials.gov website; 2. AstraZeneca Pharmaceuticals LP press release. Published August 20, 2021; 3. Study NCT04625972. ClinicalTrials.gov website; 4. AstraZeneca Pharmaceuticals LP press release. Published June 15, 2021; 5. Study NCT04518410. ClinicalTrials.gov website; 6. Study NCT04723394. ClinicalTrials.gov website; 7. AstraZeneca Pharmaceuticals LP press release. Published June 15, 2021; 8. Study NCT04501978. ClinicalTrials.gov website; 9. Study NCT04315948. ClinicalTrials.gov website.

Indications for Evusheld Use

UK, EU (2022, March), USFDA (2021, December, EUA) for COVID-19

Pre-exposure prophylaxis

- Adults, aged≥12 years and BW≥40 kg
- not currently infected or exposed to SARS-CoV-2 and
- inadequate immune response or not recommend to COVID-19 vaccination

Emergency Use Authorization (EUA)

- Serious or Life-Threatening Disease or Condition
- Evidence of Effectiveness
- Risk-Benefit Analysis
- No Alternatives

Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals



For Immediate Release: December 08, 2021

reduction in risk of developing COVID-19 was maintained for Evusheld recipients through six months. The safety and effectiveness of Evusheld for use in the pre-exposure prevention of COVID-19 continue to be evaluated.

Moderate to severe immunocompromising conditions → suboptimal COVID-19 vaccine response

Active treatment for solid tumor and hematologic malignancies

Receipt of solid-organ transplant and taking immunosuppressive therapy

Receipt of CAR-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy)*

Moderate or severe primary immunodeficiency (eg, DiGeorge, Wiskott-Aldrich syndromes)

Advanced or untreated HIV infection (CD4 cell count <200 cells/microL, history of AIDS-defining illness without immune reconstitution, clinical manifestations of symptomatic HIV)

•Active treatment with: High-dose corticosteroids (ie, \geq 20 mg prednisone or equivalent \geq 2 weeks)

•Alkylating agents

•Antimetabolites

•Transplant-related immunosuppressive drugs

•Cancer chemotherapeutic agents classified as severely immunosuppressive

•TNF blockers

•Other biologic agents that are immunosuppressive or immunomodulatory



Problems of HD-COVID during phase 3 outbreak in Bangkok (up to Aug 2021, 2nd pandemic)

		new HD-COVID	mortality(%)	new COVID cases
April	HD	25	8%	1,078
	PD	14	14%	
May	HD	5 – 10/day	33%	3,226
June	HD	10 - 30/day	48%	3,644
July	HD	10 – 30/day	30%	3,977
Aug	HD	5 -10/day	14%	4,368

For these strategies, most of HD Covid patients were not delayed the dialysis and had taken the antiviral drugs within 1-3 days after diagnosis. we had 6 cohort HD Covid centers in Bangkok metropolitans (5/6 were private centers) >80% HD patients were vaccinated